IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMO DEVELOPMENT, LLC, AMO MANUFACTURING USA, LLC and AMO SALES AND SERVICE, INC., Plaintiffs, v. ALCON LENSX, INC., ALCON VISION, LLC, ALCON LABORATORIES, INC. and ALCON RESEARCH, LLC, Defendants.	)	C.A. No. 20-842 (CFC) **DEMAND FOR JURY TRIAL**

AMENDED COMPLAINT

Plaintiffs AMO Development, LLC, AMO Manufacturing USA, LLC, and AMO Sales and Service, Inc. (collectively, "J&J Surgical Vision") are part of Johnson & Johnson Vision, which represents the products and services of Johnson & Johnson Surgical Vision, Inc. and its affiliates. Johnson & Johnson Vision is part of Johnson & Johnson Medical Devices Companies of the Johnson & Johnson Family of Companies. J&J Surgical Vision, for its Complaint against Defendants Alcon LenSx, Inc., Alcon Vision, LLC, Alcon Laboratories, Inc., and Alcon Research, LLC (collectively, "Alcon"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent and copyright infringement. The infringed patents are U.S. Patent No. 8,394,084 ("the '084 patent"), U.S. Patent No. 8,403,921 ("the '921 patent"), U.S. Patent No. 8,425,497 ("the '497 patent"), U.S. Patent No. 8,500,724 ("the '724 patent"), U.S. Patent No. 8,709,001 ("the '001 patent"), U.S. Patent No. 9,095,415 ("the '415 patent"), U.S. Patent No. 9,101,448 ("the '448 patent"), U.S. Patent No. 9,107,732 ("the '732 patent"), U.S. Patent No. 9,125,725 ("the '725 patent"), U.S. Patent No. 9,233,023 ("the '023 patent"), U.S.

Patent No. 9,233,024 ("the '024 patent"), U.S. Patent No. 9,474,648 ("the '648 patent"), U.S. Patent No. 9,693,903 ("the '903 patent"), U.S. Patent No. 9,693,904 ("the '904 patent"), U.S. Patent No. 10,376,356 ("the '356 patent"), and U.S. Patent No. 10,709,548 ("the '548 patent") (collectively, the "Asserted Patents"), based on Alcon's manufacture, use, offer to sell, sale, and import/export of the LenSx® Laser System ("LenSx"). The '084 patent, '921 patent, '497 patent, '724 patent, '001 patent, '415 patent, '448 patent, '732 patent, '725 patent, '648 patent, '903 patent, and '904 patent are referred to collectively herein as the "Palanker Patents." The '023 patent, '024 patent, '356 patent, and '548 patent are referred to collectively herein as the "Culbertson Patents."

2. The infringed copyrights ("Asserted Copyrights") protect the computer programs that operate J&J Surgical Vision's IntraLase® FS Model 2 and Model 3 Laser systems and iFS® Advanced Femtosecond Laser systems (collectively, the "iFS® Laser").

PARTIES

3. Plaintiff AMO Development, LLC ("AMO Development") is a Delaware company with a principal place of business at 1700 East St. Andrew Place, Santa Ana, California. AMO Development is an indirect subsidiary of Johnson & Johnson Surgical Vision, Inc.

4. Plaintiff AMO Manufacturing USA, LLC ("AMO Manufacturing") is a Delaware company with a principal place of business at 510 Cottonwood Drive, Milpitas, California. AMO Manufacturing is an indirect subsidiary of Johnson & Johnson Surgical Vision, Inc.

5. Plaintiff AMO Sales and Service, Inc. ("AMO Sales and Service") is a Delaware corporation with a principal place of business at 1700 East St. Andrew Place, Santa Ana, California. AMO Sales and Service is an indirect subsidiary of Johnson & Johnson Surgical Vision, Inc.

6. Upon information and belief, Defendant Alcon LenSx, Inc. ("Alcon LenSx") is a Delaware corporation with a principal place of business at 6201 South Freeway, Fort Worth, Texas.

7. Upon information and belief, Defendant Alcon Vision, LLC ("Alcon Vision") is a Delaware company with a principal place of business at 6201 South Freeway, Fort Worth, Texas.

8. Upon information and belief, Defendant Alcon Laboratories, Inc. ("Alcon Laboratories") is a Delaware corporation with a principal place of business at 6201 South Freeway, Fort Worth, Texas.

9. Upon information and belief, Defendant Alcon Research, LLC ("Alcon Research") is a Delaware company with a principal place of business at 6201 South Freeway, Fort Worth, Texas.

JURISDICTION AND VENUE

10. This action arises under the patent laws of the United States, Title 35 of the United States Code, and the copyright laws of the United States, Title 17 of the United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. The Court has personal jurisdiction over Alcon LenSx because it is a Delaware corporation and, upon information and belief, has regularly and systematically transacted business in Delaware and has committed acts of patent and copyright infringement in Delaware.

12. The Court has personal jurisdiction over Alcon Vision because it is a Delaware company and, upon information and belief, has regularly and systematically transacted business in Delaware and has committed acts of patent and copyright infringement in Delaware.

13. The Court has personal jurisdiction over Alcon Laboratories because it is a Delaware corporation and, upon information and belief, has regularly and systematically

transacted business in Delaware and has committed acts of patent and copyright infringement in Delaware.

14. The Court has personal jurisdiction over Alcon Research because it is a Delaware company and, upon information and belief, has regularly and systematically transacted business in Delaware and has committed acts of patent and copyright infringement in Delaware.

15. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(a) and (b).

BACKGROUND

The Asserted Patents

16. The ’084 patent is entitled “Apparatus for patterned plasma-mediated laser trephination of the lens capsule and three dimensional phaco-segmentation,” and was duly and legally issued on March 12, 2013. A true and correct copy of the ’084 patent is attached hereto as Exhibit A.

17. The ’921 patent is entitled “Method and apparatus for patterned plasma-mediated laser trephination of the lens capsule and three dimensional phaco-segmentation,” and was duly and legally issued on March 26, 2013. A true and correct copy of the ’921 patent is attached hereto as Exhibit B.

18. The ’497 patent is entitled “Method and apparatus for patterned plasma-mediated laser trephination of the lens capsule and three dimensional phaco-segmentation,” and was duly and legally issued on April 23, 2013. A true and correct copy of the ’497 patent is attached hereto as Exhibit C.

19. The ’724 patent is entitled “Method and apparatus for patterned plasma-mediated laser trephination of the lens capsule and three dimensional phaco-segmentation,” and was duly and legally issued on August 6, 2013. A true and correct copy of the ’724 patent is attached hereto as Exhibit D.

20. The ’001 patent is entitled “Method and apparatus for patterned plasma-mediated laser trephination of the lens capsule and three dimensional phaco-segmentation,” and was duly and legally issued on April 29, 2014. A true and correct copy of the ’001 patent is attached hereto as Exhibit E.

21. The ’415 patent is entitled “Method and apparatus for patterned plasma-mediated laser trephination of the lens capsule and three dimensional phaco-segmentation,” and was duly and legally issued on August 4, 2015. A true and correct copy of the ’415 patent is attached hereto as Exhibit F.

22. The ’448 patent is entitled “Method and apparatus for patterned plasma-mediated laser trephination of the lens capsule and three dimensional phaco-segmentation,” and was duly and legally issued on August 11, 2015. A true and correct copy of the ’448 patent is attached hereto as Exhibit G.

23. The ’732 patent is entitled “Method and apparatus for patterned plasma-mediated laser trephination of the lens capsule and three dimensional phaco-segmentation,” and was duly and legally issued on August 18, 2015. A true and correct copy of the ’732 patent is attached hereto as Exhibit H.

24. The ’725 patent is entitled “Method and apparatus for patterned plasma-mediated laser trephination of the lens capsule and three dimensional phaco-segmentation,” and was duly and legally issued on September 8, 2015. A true and correct copy of the ’725 patent is attached hereto as Exhibit I.

25. The ’023 patent is entitled “Method and apparatus for creating ocular surgical and relaxing incisions,” and was duly and legally issued on January 12, 2016. A true and correct copy of the ’023 patent is attached hereto as Exhibit J.

26. The ’024 patent is entitled “Method and apparatus for creating ocular surgical and relaxing incisions,” and was duly and legally issued on January 12, 2016. A true and correct copy of the ’024 patent is attached hereto as Exhibit K.

27. The ’648 patent is entitled “Apparatus for patterned plasma-mediated laser ophthalmic surgery,” and was duly and legally issued on October 25, 2016. A true and correct copy of the ’648 patent is attached hereto as Exhibit L.

28. The ’903 patent is entitled “Apparatus for patterned plasma-mediated laser ophthalmic surgery,” and was duly and legally issued on July 4, 2017. A true and correct copy of the ’903 patent is attached hereto as Exhibit M.

29. The ’904 patent is entitled “Apparatus for patterned plasma-mediated laser ophthalmic surgery,” and was duly and legally issued on July 4, 2017. A true and correct copy of the ’904 patent is attached hereto as Exhibit N.

30. The ’356 patent is entitled “Method and apparatus for creating ocular surgical and relaxing incisions,” and was duly and legally issued on August 13, 2019. A true and correct copy of the ’356 patent is attached hereto as Exhibit O.

31. The ’548 patent is entitled “Method and apparatus for creating ocular surgical and relaxing incisions,” and was duly and legally issued on July 14, 2020. A true and correct copy of the ’548 patent is attached hereto as Exhibit P.

32. AMO Development is the owner by assignment of each of the Asserted Patents.

33. AMO Manufacturing holds the exclusive license to manufacture products under the Asserted Patents, including the right to enforce the Asserted Patents jointly with AMO Development.

34. AMO Sales and Service holds the exclusive license to offer to sell and sell products under the Asserted Patents, including the right to enforce the Asserted Patents jointly with AMO Development.

The Asserted Copyrights

35. The copyright in the initial version of the IntraLase FS Model 2/Model 3 Software was registered with the U.S. Copyright Office as TX0008892568. A copy of the registration certificate is attached as Exhibit Q.

36. The copyright in IntraLase FS Model 2/Model 3 Software Version 1.01 was registered with the U.S. Copyright Office as TX0008892570. A copy of the registration certificate is attached as Exhibit R.

37. The copyright in IntraLase FS Model 2/Model 3 Software Version 1.02 was registered with the U.S. Copyright Office as TX0008892579. A copy of the registration certificate is attached as Exhibit S.

38. The copyright in IntraLase FS Model 2/Model 3 Software Version 1.03 was registered with the U.S. Copyright Office as TX0008892616. A copy of the registration certificate is attached as Exhibit T.

39. The copyright in IntraLase FS Model 2/Model 3 Software Version 1.04 was registered with the U.S. Copyright Office as TX0008892571. A copy of the registration certificate is attached as Exhibit U.

40. The copyright in IntraLase FS Model 2/Model 3 Software Version 1.05 was registered with the U.S. Copyright Office as TX0008892576. A copy of the registration certificate is attached as Exhibit V.

41. The copyright in IntraLase FS Model 2/Model 3 Software Version 1.06 was registered with the U.S. Copyright Office as TX0008892583. A copy of the registration certificate is attached as Exhibit W.

42. The copyright in IntraLase FS Model 2/Model 3 Software Version 1.07 was registered with the U.S. Copyright Office as TX0008892582. A copy of the registration certificate is attached as Exhibit X.

43. The copyright in IntraLase FS Model 2/Model 3 Software Version 1.08 was registered with the U.S. Copyright Office as TX0008892586. A copy of the registration certificate is attached as Exhibit Y.

44. The copyright in IntraLase FS Model 2/Model 3 Software Version 1.10 was registered with the U.S. Copyright Office as TX0008892565. A copy of the registration certificate is attached as Exhibit Z.

45. The copyright in IntraLase FS Model 2/Model 3 Software Version 1.12 was registered with the U.S. Copyright Office as TX0008892585. A copy of the registration certificate is attached as Exhibit AA.

46. The copyright in iFS Advanced Femtosecond Laser Software Version 2.02 was registered with the U.S. Copyright Office as TX0008892564. A copy of the registration certificate is attached as Exhibit BB.

47. The copyright in iFS Advanced Femtosecond Laser Software Version 2.04 was registered with the U.S. Copyright Office as TX0008892567. A copy of the registration certificate is attached as Exhibit CC.

48. The copyright in iFS Advanced Femtosecond Laser Software Version 2.20 was registered with the U.S. Copyright Office as TX0008892618. A copy of the registration certificate is attached as Exhibit DD.

49. The copyright in iFS Advanced Femtosecond Laser Software Version 2.30 was registered with the U.S. Copyright Office as TX0008892614. A copy of the registration certificate is attached as Exhibit EE.

50. The copyright in iFS Advanced Femtosecond Laser Software Version 2.50 was registered with the U.S. Copyright Office as TX0008892580. A copy of the registration certificate is attached as Exhibit FF.

51. The copyright in iFS Advanced Femtosecond Laser Software Version 2.60 was registered with the U.S. Copyright Office as TX0008892621. A copy of the registration certificate is attached as Exhibit GG.

52. The copyright in iFS Advanced Femtosecond Laser Software Version 2.70 was registered with the U.S. Copyright Office as TX0008892612. A copy of the registration certificate is attached as Exhibit HH.

53. The above copyright registrations were made prior to filing this action for infringement of the Asserted Copyrights.

54. AMO Development owns the Asserted Copyrights (and all rights thereunder, including the right to file suit), either through a written transfer agreement or as the original work-for-hire author of the computer programs.

Cataract Surgery

55. Cataracts result from clouding of the crystalline lens of the eye. Left untreated, they can impair vision and ultimately result in blindness.

56. To restore vision in cataract patients, the diseased lens can be removed and replaced by an artificial intraocular lens. Cataract surgery is one of the most common surgical procedures in the United States.

57. Manual cataract surgery involves several challenging steps that require great expertise by the surgeon. To access the diseased lens, the surgeon must perform a capsulorhexis, in which a portion of the anterior capsule surrounding the lens is removed. Manual capsulorhexis involves freehand pulling and tearing of capsular tissue and presents the risk of unwanted tears in the capsule, which can increase surgical time and lead to poor clinical outcomes. Phacoemulsification is then used to break up the diseased lens into smaller pieces, typically using an ultrasonic probe, so that it can be removed. Extended use of the ultrasonic probe can cause excess cumulative dissipated energy in the eye and endothelial cell loss.

The Patented Inventions and Copyrighted Works

58. J&J Surgical Vision, through its OptiMedica subsidiary, was a pioneer in the field of laser cataract surgery. Founded in 2004, OptiMedica envisioned that laser surgery could be performed deep below the surface of the eye, using an ultrafast "femtosecond" laser, to treat disorders such as cataracts.

59. The Asserted Patents disclose and claim novel inventions that address the most important and difficult steps of cataract surgery, resulting in improved patient care and superior clinical outcomes.

60. The inventors of the Asserted Patents developed apparatus and methods for laser cataract surgery that enable the often difficult steps of cataract surgery to be performed precisely, consistently, and safely. One key insight was to incorporate an advanced imaging technology known as optical coherence tomography ("OCT") to identify structures in the anterior segment of the eye and to use the image data to control the laser to safely perform laser cataract surgery on

the anterior capsule and crystalline lens of the eye. The laser is also configured to make controlled cataract incisions that allow entry into the eye and can promote wound healing and ensure sterility, together with relaxing incisions that precisely and reliably reduce astigmatism in cataract patients.

61. J&J Surgical Vision's patented technology revolutionized cataract surgery by allowing ophthalmologists to perform laser surgery on the anterior capsule and crystalline lens with greater precision, safety, and ease than is possible in manual cataract surgery. The laser can perform an anterior capsulotomy with greater circularity, and with decreased likelihood of nicks and tears, which allows for improved positioning and centration of the intraocular lens. This dramatic advance is described in a November 2010 cover article published by the inventors in *Science Translational Medicine*, entitled "Femtosecond Laser-Assisted Cataract Surgery with Integrated Optical Coherence Tomography." As shown, OCT-guided laser cataract surgery (**B**) provided for the extraction of capsular tissue with far greater precision and reproducibility compared to manual cataract surgery (**A**):

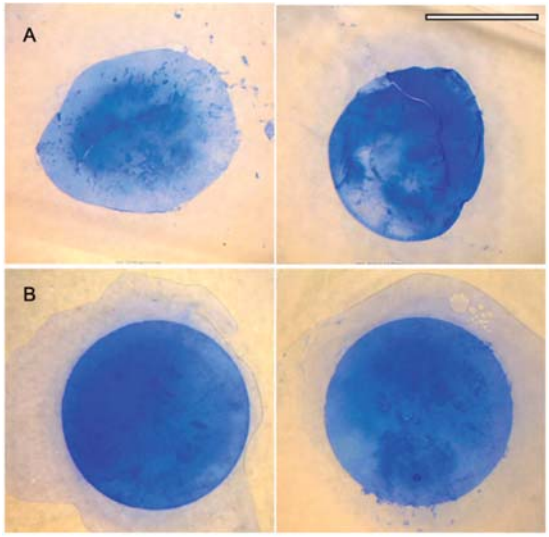
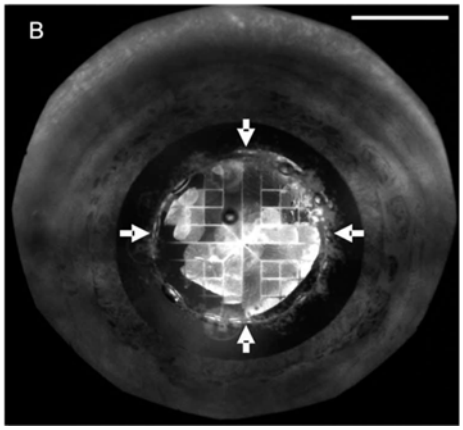


Fig. 7. Precision and reproducibility of lens capsule extraction. (**A** and **B**) Representative examples of the human lens capsule extracted after (A) manual capsulorhexis and (B) laser capsulotomy. Scale bar, 3 mm.

62. The OCT-guided laser also can make cuts in the diseased lens in a technique known as lens fragmentation, which reduces the amount of potentially damaging ultrasonic energy needed

for phacoemulsification. As shown by the inventors in their *Science Translational Medicine* article, OCT-guided laser cataract surgery can be used to segment the lens tissue, which allows the surgeon to remove the diseased lens faster and with less ultrasonic energy:



Segmentation of the diseased lens in this manner minimizes potential endothelial injury and results in faster visual recovery.

63. The inventors' work ultimately led to the Catalys® Precision Laser System, which was cleared by the U.S. Food and Drug Administration ("FDA") for commercial sale in 2011. This system employs the patented technology described and claimed in the Asserted Patents. The Catalys® Precision Laser System is marked with the Asserted Patents in accordance with 35 U.S.C. § 287(a).

64. In addition to the Catalys® Precision Laser System, J&J Surgical Vision manufactures the iFS® Laser, another ophthalmic surgical laser that is principally used for LASIK surgery. In addition to the laser hardware, the iFS® Laser includes proprietary software that directs the laser based on each patient's surgical parameters, provides a graphical user interface to aid the surgeon in comfortably performing the procedure, and performs various pre-procedure system checks and calibration checks, among other functions. As described below, there have been several versions of the iFS® Laser software released over the years.

65. The iFS® Laser software is highly complex and creative, and is a key component of the laser equipment it operates. The software enables the surgeon to cut a corneal flap at predetermined parameters within the eye's corneal tissue. A surgeon can input a patient's precise surgical parameters into the software prior to surgery. The software then performs pre-procedure system checks to verify the readiness of the laser, and directs the laser to create a precise corneal flap based on the input parameters. The software also provides a graphical user interface, patient and surgeon database, system utilities, diagnostic and calibration tools, and error management. The authors of the iFS® Laser software made numerous creative decisions in writing the computer programs (including all of the registered updates) that were not dictated by hardware or other external functional constraints, including decisions regarding the structure, sequence, and organization of the program, the file system structure and naming conventions, the content of error messages, and the graphical user interface.

66. The iFS® Laser was initially developed by AMO Development's predecessor, IntraLase Corporation ("IntraLase"), which was founded in 1997 by Dr. Ron Kurtz and Dr. Tibor Juhasz. IntraLase's primary line of business was the development of computer-controlled ophthalmic lasers for use in LASIK procedures. After releasing an initial model of such a laser in 2001, IntraLase released two new models (IntraLase® Model 2 and Model 3) in approximately November 2003 and June 2005, respectively. Those models utilized a different software program developed by IntraLase employees. That software was used in the corneal incision process, was designed for a new version of the operating system, and provided other functionality. As reflected in the source code files for Version 1.0 of the software, the principal author was an IntraLase employee named Peter Goldstein.

67. Employees at J&J Surgical Vision's predecessors periodically revised and updated the software that operated the IntraLase® Model 2 and Model 3 systems through 2007 (Versions 1.01 to 1.12), adding new creative elements to the software. As reflected in the source code and other documentation, Mr. Goldstein was among the authors of these revisions.

68. Around 2008, J&J Surgical Vision's predecessors released a new version of its system called the iFS® Advanced Femtosecond Laser. The software that operated that newer laser system built upon the existing source code for the IntraLase® Model 2 and Model 3 systems, with IntraLase employees adding additional creative elements to it. As reflected in the source code and related documentation for this version, Mr. Goldstein and another IntraLase employee, Kostadin Vardin, were among authors of that code.

69. The software for the iFS® Advanced Femtosecond Laser has been periodically updated since it was first released, with a number of versions released between 2008 and 2016, adding new creative elements. As reflected in the source code, Mr. Goldstein and Mr. Vardin were among the authors of the first such update (Version 2.02), which was developed largely over the course of 2007 and 2008 and released in early 2009.

70. Each version of the iFS® Laser software is a copyrightable computer program under the U.S. Copyright Act, and the Asserted Copyrights came into existence upon creation and fixation of each such version. The Asserted Copyrights encompass all copyrightable expression embodied in the iFS® Laser computer programs, including source code, object code, user interfaces, structure, sequence and organization, and all other literal and non-literal elements of those computer programs.

Alcon's Infringement of J&J Surgical Vision's Patents

71. Alcon manufactures and markets the LenSx in the United States. The LenSx is an OCT-guided laser system designed and intended to perform an anterior capsulotomy and lens

fragmentation. The LenSx is also designed to make cataract incisions and relaxing incisions during cataract surgery. The LenSx user interface includes five Programs:

72. Upon information and belief, Alcon's customers in the United States and within this judicial district have used and continue to use the LenSx in accordance with instructions provided by Alcon.

73. The LenSx directly competes against J&J Surgical Vision's Catalys® Precision Laser System in a highly specialized technical market.

74. Upon information and belief, Alcon LenSx makes, uses, offers to sell, and/or sells the LenSx and consumables in the United States, and supplies or causes to be supplied the LenSx and consumables from the United States for use abroad. Upon information and belief, the LenSx is manufactured at facilities operated by Alcon LenSx in the United States, and is distributed both domestically and internationally. Upon information and belief, Alcon LenSx and its employees authored at least portions of the Operator's Manual for the LenSx, which instructs customers how to perform anterior capsulotomy, lens fragmentation, cataract incisions, and relaxing incisions using the LenSx in an manner that infringes the Asserted Patents.

75. Upon information and belief, Alcon Vision makes, uses, offers to sell, and/or sells the LenSx and consumables in the United States, and supplies or causes to be supplied the LenSx and consumables from the United States for use abroad. Upon information and belief, Alcon Vision acts as a distributor for the LenSx both domestically and internationally. Upon information and belief, Alcon Vision is responsible for repair and maintenance of LenSx systems used by its customers.

76. Upon information and belief, Alcon Laboratories makes, uses, offers to sell, and/or sells the LenSx and consumables in the United States, and supplies or causes to be supplied the LenSx and consumables from the United States for use abroad. Upon information and belief, Alcon Laboratories is involved in the manufacture, distribution, and export of the LenSx. Upon information and belief, Alcon Laboratories sells consumables for the LenSx, including but not limited to the LenSx SoftFit Patient Interface, and charges customers for using the LenSx on a per-procedure basis.

77. Upon information and belief, Alcon Research makes, uses, offers to sell, and/or sells the LenSx and consumables in the United States, and supplies or causes to be supplied the LenSx and consumables from the United States for use abroad. Upon information and belief, Alcon Research is involved in the manufacture, distribution, and export of the LenSx.

78. Upon information and belief, Alcon LenSx, Alcon Vision, Alcon Laboratories, and Alcon Research act as agents of each other and/or operate in concert as integrated parts of the same business group with respect to the LenSx.

Alcon's Knowledge and Willful Patent Infringement

79. The LenSx was originally developed by LenSx Lasers, Inc., which was founded well after OptiMedica filed its original provisional patent application that resulted in the Palanker Patents. Its founders and other early employees, including key personnel who designed the hardware and software incorporated into the LenSx, were previously affiliated with J&J Surgical Vision.

80. Alcon acquired LenSx Lasers, Inc. in July 2010 and commercially launched the LenSx in the United States in 2011. At the time, there was a small number of competitors seeking to commercialize laser cataract surgery systems, including Alcon and J&J Surgical Vision. Upon information and belief, at that time, Alcon (including its predecessors) was a sophisticated

company that closely tracked the activities and patent filings of its competitors in a highly specialized technical market. Upon information and belief, Alcon has continued to track the activities and patent filings of its competitors.

81. WO 2006/074469, the international counterpart patent application to the Palanker Patents, published on July 13, 2006. Alcon was aware of that application on or about July 30, 2008, and Alcon's knowledge is confirmed by citation to WO 2006/074469 in connection with its own patent applications. WO 2006/074469 is well-known to Alcon given that it has been cited in connection with at least 10 Alcon patent applications since 2006. Upon information and belief, Alcon (including its predecessors) was aware of this patent application and its applicability to the LenSx when it commercially launched the LenSx in the United States. Upon information and belief, given the relationship of this application to the Palanker Patents, Alcon's knowledge of WO 2006/074469 also resulted in knowledge of the Palanker Patents at or about the time that they issued.

82. US 2006/0195076, the United States patent application that resulted in the Palanker Patents, published on August 31, 2006. Alcon was aware of that application no later than February 25, 2008, and Alcon's knowledge is confirmed by citation to US 2006/0195076 in connection with its own patent applications. US 2006/0195076 is well-known to Alcon given that it has been cited in connection with at least 30 Alcon (including its predecessors) patent applications since 2006. Upon information and belief, Alcon (including its predecessors) was aware of this patent application and its applicability to the LenSx when it commercially launched the LenSx in the United States. Upon information and belief, given the relationship of this application to the Palanker Patents, Alcon's knowledge of US 2006/0195076 also resulted in knowledge of the Palanker Patents at or about the time that they issued.

83. US 2008/0281303, the United States patent application that resulted in the Culbertson Patents, published on November 13, 2008. Alcon was aware of that application no later than April 6, 2010, and Alcon's knowledge is confirmed by its citation to US 2008/0281303 in connection with its own patent applications. US 2008/0281303 is well-known to Alcon given that it has been cited in connection with at least 21 Alcon (including its predecessors) patent applications since 2010. Upon information and belief, Alcon (including its predecessors) was aware of this patent application and its applicability to the LenSx when it commercially launched the LenSx in the United States. Upon information and belief, given the relationship of this application to the Culbertson Patents, Alcon's knowledge of US 2008/0281303 also resulted in knowledge of the Culbertson Patents at or about the time that they issued.

84. Upon information and belief, when Alcon acquired LenSx Lasers, Inc. in July 2010, the acquisition agreement included an Escrow Balance that was intended to cover any one-time payment or future royalty payments arising from claims of patent infringement. Upon information and belief, the acquisition agreement also contemplated that the Alcon and the prior owners of LenSx Lasers, Inc. would equally share liability for payments arising from patent infringement up to $400 million. Upon information and belief, these provisions of the acquisition agreement were included to address the risk of liability arising from the then-pending patent applications that resulted in the Asserted Patents. Upon information and belief, Alcon knew that the manufacture, use, offer to sell, and/or sale of the LenSx would infringe patents that issued from the then-pending patent applications, and/or subjectively believed that there was a high probability of infringement and took deliberate actions to avoid learning these facts.

85. J&J Surgical Vision's patent rights were well-known within the industry. For example, the inventors described their patented technology in a November 2010 cover article for

Science Translational Medicine, entitled "Femtosecond Laser-Assisted Cataract Surgery with Integrated Optical Coherence Tomography." Upon information and belief, Alcon was familiar with and had reviewed that article prior to the commercial launch of the LenSx. The article provided notice that J&J Surgical Vision's predecessor "OptiMedica has filed patents on the technology described in the paper," specifically identifying patent applications that resulted in the Asserted Patents.

86. J&J Surgical Vision's patent rights were also described in a March 2011 article published in *Cataract & Refractive Surgery Today*, entitled "The Origins of Laser Cataract Surgery." Upon information and belief, Alcon authorized William J. Link, the former Chairman of LenSx Lasers, Inc., be interviewed for that article on its behalf. Upon information and belief, Alcon was familiar with and had reviewed that article prior to the commercial launch of the LenSx. The article described J&J Surgical Vision's pending patent applications that led to the Asserted Patents. A representative of J&J Surgical Vision's predecessor was quoted as saying, "There's a lot of intellectual property that we filed early that was very forward-thinking, and it was all about image-guidance of femtosecond laser for cataract, capsulotomy, fragmentation, softening, corneal incisions, astigmatic correction, and so those things we've been thinking about since day 1."

87. On February 25, 2013, a press release announced "OptiMedica Granted Fundamental Patent on Laser Cataract Surgery by U.S. Patent & Trademark Office." The press release indicated that the '084 patent will issue on March 12, 2013, and that "[t]he U.S. patent supporting Catalys is one in a series that OptiMedica has filed for the system and its underlying technology worldwide." Upon information and belief, Alcon was aware of this press release shortly after it issued.

88. The ’084 patent, one of the Palanker Patents, issued on March 12, 2013. Alcon was aware of that patent, and upon information and belief its applicability to the LenSx, no later than April 5, 2013. Alcon’s knowledge is confirmed by its citation to the ’084 patent in connection with its own patent applications. Alcon’s identification of that patent very shortly after its issuance indicates that Alcon was tracking at least the application that resulted in the ’084 patent even before the patent issued. Upon information and belief, given the relationship of this patent to the other Palanker Patents, Alcon’s knowledge of the ’084 patent also resulted in knowledge of the other Palanker Patents at or about the time that they issued.

89. On March 24, 2020, J&J Surgical Vision identified each of the Palanker Patents to Alcon and explained that the manufacture, use, offer to sell, and/or sale of the LenSx infringes the Palanker Patents. On April 14, 2020, J&J Surgical Vision provided exemplary claim charts that showed how claims of the Palanker Patents read on the LenSx. J&J Surgical Vision also requested Alcon identify any limitations of the patent claims that it contends are not met by the LenSx. Alcon failed to identify any missing limitation of the patent claims in response to that correspondence.

90. On July 14, 2020, J&J Surgical Vision identified each of the Culbertson Patents to Alcon and explained that the manufacture, use, offer to sell, and/or sale of the LenSx infringes the Culbertson Patents. On August 4, 2020, J&J Surgical Vision provided exemplary claim charts that showed how claims of each of the Culbertson Patents read on the LenSx.

91. Alcon also had knowledge of the Asserted Patents because the Catalys® Precision Laser System is marked with the Asserted Patents pursuant to 35 U.S.C. § 287(a).

92. Upon information and belief, at the time it learned of the Asserted Patents, Alcon knew that the patented technology was fundamental to the operation and success of the LenSx. For example, Alcon stated: “the LenSx® laser uses a range of highly advanced technologies – including

integrated optical coherence tomography (OCT) – to capture incredibly precise, high-resolution images of your eyes. These images – and the measurements and data they provide – are then used to plan and perform a surgery to exacting specifications not attainable with traditional surgery."

93. Given the similarity of the Asserted Patents to the technology incorporated in the LenSx and touted in Alcon's product literature, Alcon's knowledge of the Asserted Patents would immediately have given it knowledge that the LenSx and its use infringe the Asserted Patents.

94. Despite its knowledge of the Asserted Patents and the LenSx's design, operation, and use, Alcon has knowingly and willfully infringed and continues to knowingly and willfully infringe the patents by making, using, offering to sell, and/or selling the LenSx, and instructing its customers to use the LenSx in a manner that infringes the Asserted Patents. Alcon has acted despite a risk of infringement that was either known or so obvious that it should have been known. Upon information and belief, after learning of the Asserted Patents, Alcon has not made any changes to the LenSx (or its instructions for use) in order to avoid infringement. Alcon's knowing infringement of the Asserted Patents is thus wanton, malicious, deliberate, consciously wrongful, flagrant, egregious, willful, and in bad faith.

Theft of the Copyrighted Computer Programs

95. Dr. Kurtz left IntraLase Corp. to found LenSx Lasers, Inc. Soon thereafter, LenSx hired a number of research and development personnel from J&J Surgical Vision's predecessor, including Mr. Goldstein in in or about 2008, Dr. Juhasz (who was named Chief Technology Officer of LenSx) in or about 2008, and Mr. Vardin (who was named Principal Software Engineer for LenSx) in or about 2009. Mr. Goldstein and Mr. Vardin each had direct access to the iFS® Laser computer programs.

96. Upon information and belief, LenSx incorporated one or more protected elements from the copyrighted iFS® Laser computer programs into the software for the LenSx, without authorization.

97. Upon information and belief, the theft of the iFS® Laser software code allowed LenSx to accelerate the development of its laser system. The LenSx received clearance from the FDA for anterior capsulotomies in August 2009, and FDA clearance for corneal incisions in December 2009.

98. Upon information and belief, Alcon unlawfully used and is continuing to use J&J Surgical Vision's copyrighted computer programs (or copyrightable elements thereof) as part of the software that operates the LenSx. The installed version of the LenSx software (at least as of Version 2.20.02) exhibits an overwhelming number of telltale signs of copying of J&J Surgical Vision's copyrighted computer programs, including but not limited to the following:

a. The LenSx® file system mirrors the file structure of an iFS® Laser, with file folders with identical names, including "*_energy*", "*_fact*", "*_io*", "*_manager*", and "*_pattern*".

b. The LenSx® includes a number of on-screen instructions identical to those on an iFS® Laser, right down to the punctuation and nonstandard capitalization, *e.g.*, "Insert Memory Stick into USB Port, Wait for Light to Go Off …" and "Make Sure a Memory Stick is Inserted into USB Port!".

c. The LenSx object code files includes over 300 references to file, function, and object names and other text that are identical to and originate in the iFS® Laser source code—far too many to be mere coincidence.

d. The object code file for the LenSx software module controlling the beam steering process (*beam_control*) references unique function names that were originally in the iFS®

Laser source code ("*bsx_thread*", "*bsy_thread*", "*check_inputs*", "*read_z_enc_value*", "*set_outputs*", "*wait_beam_cmnd*"). The same object code file includes at least fifty unique data object names that were originally in the iFS® Laser source code (*e.g.*, "*estop_coid*", "*estop_msg*", "*mutex*", "*ok_for_ftsw_off*", "*ok_for_ftsw_on*", "*passlevel*", "*ptrn_file*", "*ptrn_rmsg*", "*ptrn_smsg*"). That file also contains error codes and other text that are identical to, and originate in, the iFS® Laser source code (*e.g.*, "*Non Positive Spot Separation Value – Fatal Error*", "*Invalid Service Code from Client Process*", "*Minimum Z Value Exceeds Maximum Depth in Contact Glass*", "*< beam > - Could Not Locate ESTOP*").

e. The object code file for the LenSx software module responsible for positioning the laser to the proper position (*scanners*) includes at least seventeen unique function names (*e.g.*, "*dig_to_ana*", "*get_aio_base_address*", "*gui_comm_request*", "*init_dio_board*", "*read_z_enc_value*", "*sig_handlr*"), seventy-five unique data object names (*e.g.*, "*aio_base*", "*aio_reg*", "*lpoint*", "*rr_divider*"), and other text (e.g., "*/galvo_points*", "*No Additional Information Available*", "*Invalid Pattern ID from Client Process*"), that is identical to, and originate in, the iFS® Laser source code.

f. The LenSx exhibits similar or identical behaviors to various error conditions. For example, when the "*/_io/errorint*" process is removed from the iFS® Laser, it will display the following error: "*< laser > Failed to Spawn ERRORINT . . . Failed to Start Child Processes !*" When the "*/_io/errirq*" process was removed from the LenSx, the LenSx displayed a nearly identical error message, including the extra space before the final exclamation mark: "*< laser > Failed to Spawn errirq . . . Failed to Start Child Processes !*"

g. Both the iFS® Laser and LenSx systems register process names with the operating system to facilitate interprocess communication. In the iFS® Laser, the registered process

name matches the name of the file containing the code for that process. For example, the iFS® Laser registers a process name with the operating system called "***ERRORINT***", corresponding to a process file called "*/_io/**errorint***." The LenSx contains registered process names that are identical to those in the iFS® Laser, even where the underlying process files in the LenSx do not match the corresponding process name. For instance, in the LenSx, there is a process file named "*/_io/**errirq***" but when the LenSx registers the corresponding process name with the operating system, it uses the same process name as the iFS® Laser: "***ERRORINT***." This in particular is evidence that Alcon attempted to cover up the evidence of copying by changing certain names.

99. Upon information and belief, the LenSx software continues to incorporate one or more protected elements of the copyrighted iFS® Laser computer programs. Since 2014, Alcon has made three submissions to the FDA seeking approval to market modified versions of the LenSx, based on the assertion that the modified device is "substantially equivalent" to an earlier-approved device. A review of those filings, called "section 510(k) premarket notifications," provides no indication that Alcon has replaced the LenSx software with new and original software. To the contrary, those filings suggest that any changes were only to add, rather than remove or modify, functionality. The 2016 510(k) filing indicated that software updates were to "implement the use of a planner Ethernet device for cataract surgery, re-enabling flap functionality that was previously cleared, and introducing an optional lens fragmentation pattern whose parameters are within previously cleared treatment ranges." The 2017 510(k) filing indicated that no changes to the LenSx software had been made. And the 2018 filing indicated that software updates were implemented only to support new functionality to create corneal tunnels and corneal pockets.

100. On July 14, 2020, J&J Surgical Vision informed Alcon of numerous similarities to the iFS® Laser present in the LenSx software, and invited Alcon to explain the source of those

similarities. Alcon did not deny that those similarities existed and continue to exist, and it provided no explanation for the telltale signs of copying that J&J Surgical Vision identified.

Alcon's Ongoing Acts of Copyright Infringement

101. Upon information and belief, Alcon has manufactured, and continues to manufacture, the LenSx in the United States, each of which contains one or more copies of software that incorporates one or more protected elements of the copyrighted iFS® Laser computer programs. In addition, upon information and belief, Alcon has made, and continues to make, additional copies of the LenSx software that incorporate one or more protected elements of the copyrighted iFS® Laser computer programs, including in the course of developing, testing, manufacturing, and distributing new versions of, or updates to, the LenSx software. These acts constitute unauthorized and unlawful reproduction of J&J Surgical Vision's copyrighted computer programs.

102. Upon information and belief, Alcon has created, and continues to create, modified versions of software based on the copyrighted iFS® Laser computer programs, including when developing, testing, and manufacturing new versions of the LenSx software. These acts constitute unauthorized and unlawful preparation of derivative works based upon J&J Surgical Vision's copyrighted computer programs.

103. Upon information and belief, Alcon has distributed, and continues to distribute, the LenSx within the United States, each of which contains one or more copies of software that incorporates one or more protected elements of the copyrighted iFS® Laser computer programs. In addition, upon information and belief, Alcon has distributed, and continues to distribute, within the United States, new versions of, or updates to, the LenSx software that incorporate one or more protected elements of the copyrighted iFS® Laser computer programs. These acts constitute

unauthorized and unlawful distribution of J&J Surgical Vision's copyrighted computer programs to the public.

104. Upon information and belief, Alcon also has exported, and continues to export, the LenSx, each of which contains one or more copies of software that incorporates one or more protected elements of the copyrighted iFS® Laser computer programs. In addition, upon information and belief, Alcon has exported, and continues to export, new versions of, or updates to, the LenSx software that incorporate one or more protected elements of the copyrighted iFS® Laser computer programs. These acts constitute unauthorized and unlawful exportation from the United States of works infringing J&J Surgical Vision's copyrighted computer programs.

105. Each of Alcon's LenSx customers has made, and continues to make, copies of LenSx software each time that software is loaded into the random access memory of the LenSx. In addition, upon information and belief, each of Alcon's LenSx customers also has made, and continues to make, copies of LenSx software each time they install new versions of, or software updates to, the LenSx software on the LenSx. As a result, users of the LenSx are engaged in unauthorized and unlawful reproduction of the protected elements of the copyrighted iFS® Laser computer programs that are incorporated into the LenSx software. Upon information and belief, Alcon profits from its LenSx customers' ongoing unauthorized acts of direct infringement. Specifically, Alcon sells consumable parts and receives ongoing procedure and maintenance fees from its customers based on their use of LenSx. Moreover, upon information and belief, Alcon has the right and ability to stop or limit those acts of infringement, but has declined to do so. Specifically, Alcon could decline to sell customers the necessary consumable parts, or could provide software updates that would replace the infringing software on its customers' devices. In addition, upon information and belief, Alcon has induced and/or encouraged its customers to use

the LenSx, with the knowledge that doing so would necessarily cause its customers to create unlawful and unauthorized copies of protected elements of J&J Surgical Vision's copyrighted computer programs.

106. Alcon was put on notice of its acts of copyright infringement as of July 14, 2020, when J&J Surgical Vision sent a letter identifying unambiguous evidence of such copying. Nonetheless, upon information and belief, Alcon has continued to engage in the acts of copyright infringement alleged herein.

COUNT I
Infringement of the '084 Patent

107. J&J Surgical Vision incorporates by reference the allegations set forth in paragraphs 1 through 106 as though fully set forth herein.

108. Alcon has directly and indirectly infringed, and continues to infringe, literally or under the doctrine of equivalents, one or more claims of the '084 patent, by making, using, offering to sell, and/or selling the LenSx and consumables in the United States, and supplying or causing to be supplied the LenSx and consumables from the United States for use abroad, without authority or license, in violation of 35 U.S.C. § 271.

109. For example, the LenSx meets each limitation of claim 1 of the '084 patent, which recites:

A system for cataract surgery on an eye, comprising:

a. a pulsed laser configured to produce a treatment beam which creates dielectric breakdown in a focal zone of the treatment beam within one or more tissue structures of a cataractous crystalline lens;

b. a three-dimensional, optical coherence tomography imaging assembly capable of creating a continuous depth profile of the anterior portion of the cataractous crystalline lens, the profile comprising information regarding the location of a capsule of the cataractous crystalline lens and structures within the crystalline lens, by detecting remitted illumination light from locations distributed

throughout a volume of the cataractous crystalline lens, and generating signals based upon the remitted light;

c. an optical scanning system configured to position a focal zone of the treatment beam to a targeted location in three dimensions in the crystalline lens; and

d. one or more controllers operatively coupled to the laser, optical system, and imaging assembly, and programmed to automatically:

i. scan tissues of the patient's eye with the imaging assembly so as to generate image data signals to create a continuous depth profile of at least the anterior portion of the lens;

ii. identify one or more boundaries of the one or more tissue structures of the cataractous crystalline lens based at least in part on the image data;

iii. identify one or more treatment regions based upon the boundaries; and

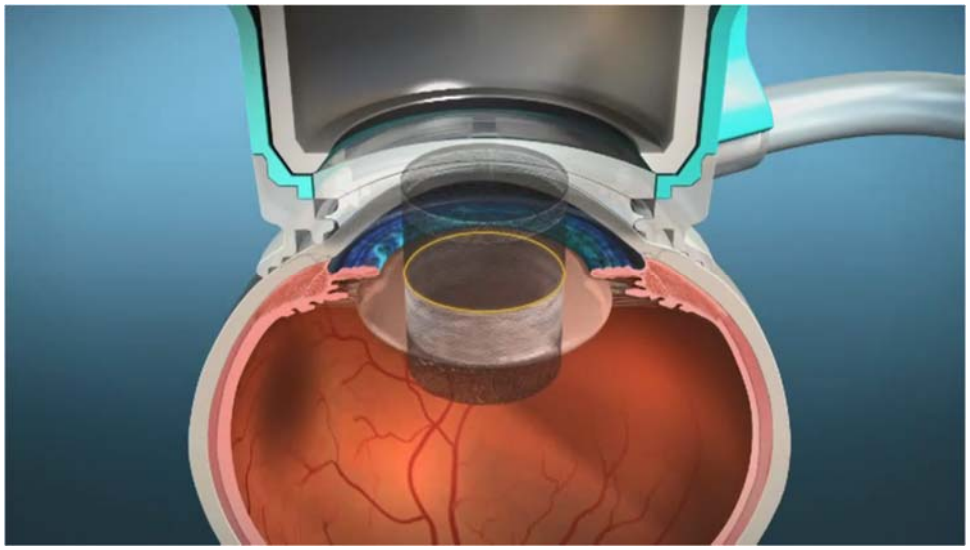
iv. operate the optical scanning system with the pulsed laser to produce a treatment beam directed in a pattern based on the one or more treatment regions so as to create a capsulotomy in the anterior portion of the lens, the treatment beam having a pulse repetition rate between about 1 kHz and about 1,000 kHz, and a pulse energy between about 1 microjoule and about 30 microjoules.

110. The LenSx is a system for cataract surgery on an eye. For example, Alcon has stated that the LenSx is "indicated for use in patients undergoing cataract surgery." Upon information and belief, the LenSx is designed and "indicated for . . . anterior capsulotomy and laser phacofragmentation during cataract surgery."

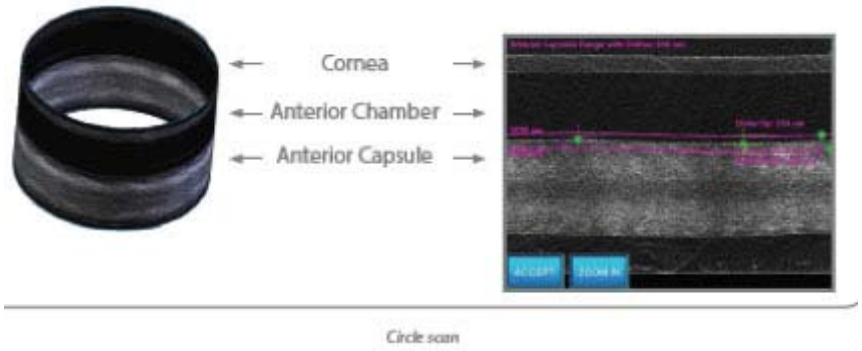
111. The LenSx has a pulsed laser configured to produce a treatment beam which creates dielectric breakdown in a focal zone of the treatment beam within one or more tissue structures of a cataractous crystalline lens. For example, Alcon has stated that the LenSx has "an ophthalmic surgical laser which uses focused femtosecond laser pulses to create incisions and to separate tissue within the lens capsule, crystalline lens, and the cornea. A femtosecond light pulse[] is focused

into a sufficiently small spot in order to achieve photodisruption of the tissue inside the focus. A tiny volume of tissue, a few microns in diameter, is thereby photodisrupted at the laser focus. A computer-controlled scanning system directs the focused laser beam throughout a three-dimensional pattern to produce an incision." Upon information and belief, the photodisruption is achieved through dielectric breakdown within the tissue structures.

112. The LenSx includes a three-dimensional, optical coherence tomography imaging assembly capable of creating a continuous depth profile of the anterior portion of the cataractous crystalline lens, the profile comprising information regarding the location of a capsule of the cataractous crystalline lens and structures within the crystalline lens, by detecting remitted illumination light from locations distributed throughout a volume of the cataractous crystalline lens, and generating signals based upon the remitted light. Upon information and belief, the LenSx uses a 3D spectral domain OCT imaging assembly. For example, Alcon has stated that its OCT imaging assembly is "a low power visible wavelength light source that is scanned throughout the transparent structures of the anterior chamber of the eye." Upon information and belief, the LenSx uses its OCT imaging assembly to generate what Alcon refers to as a circle scan. For example, Alcon has illustrated a circle scan as follows:



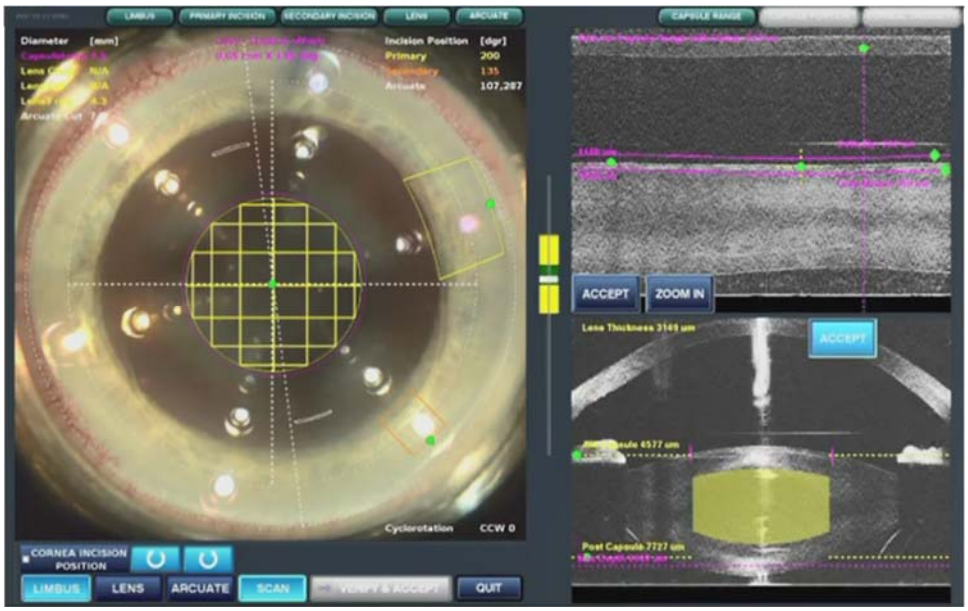
The circle scan provides a continuous depth profile of the anterior portion of the cataractous crystalline lens. For example, the depth profile is shown in the following diagram that Alcon uses to describe the circle scan:



113. The LenSx includes an optical scanning system configured to position a focal zone of the treatment beam to a targeted location in three dimensions in the crystalline lens. For example, Alcon has stated that the LenSx has "an ophthalmic surgical laser which uses focused femtosecond laser pulses to create incisions and to separate tissue within the lens capsule, crystalline lens, and the cornea. A femtosecond light pulse[] is focused into a sufficiently small spot in order to achieve photodisruption of the tissue inside the focus. A tiny volume of tissue, a few microns in diameter, is thereby photodisrupted at the laser focus. A computer-controlled scanning system directs the focused laser beam throughout a three-dimensional pattern to produce an incision."

114. The LenSx includes one or more controllers operatively coupled to the laser, optical system, and imaging assembly, and programmed to automatically scan tissues of the patient's eye with the imaging assembly so as to generate image data signals to create a continuous depth profile of at least the anterior portion of the lens. For example, Alcon has stated that in the LenSx, "[a] computer monitors and controls the beam energy, repetition rate, safety shutters, footswitch, laser

diagnostics, the position of the scanners and the position of the scanning objective lens." For example, Alcon has shown the continuous depth profile as follows:



115. The LenSx includes one or more controllers operatively coupled to the laser, optical system, and imaging assembly, and programmed to automatically identify one or more boundaries of the one or more tissue structures of the cataractous crystalline lens based at least in part on the image data. For example, Alcon has stated that in the LenSx, "[a] computer monitors and controls the beam energy, repetition rate, safety shutters, footswitch, laser diagnostics, the position of the scanners and the position of the scanning objective lens." Upon information and belief, the computer auto-finds the anterior and posterior surfaces of the lens capsule. Upon information and belief, the computer generates two horizontal lines on the OCT image and indicates the depth of the anterior capsule based at least in part on the image data, as shown in the image above.

116. The LenSx includes one or more controllers operatively coupled to the laser, optical system, and imaging assembly, and programmed to automatically identify one or more treatment regions based upon the boundaries. For example, Alcon has stated that the LenSx "includes an

optical coherence tomography (OCT) based imaging device that assists in localizing specific target locations."

117. The LenSx includes one or more controllers operatively coupled to the laser, optical system, and imaging assembly, and programmed to automatically operate the optical scanning system with the pulsed laser to produce a treatment beam directed in a pattern based on the one or more treatment regions so as to create a capsulotomy in the anterior portion of the lens, the treatment beam having a pulse repetition rate between about 1 kHz and about 1,000 kHz, and a pulse energy between about 1 microjoule and about 30 microjoules. For example, Alcon has stated that in the LenSx, "a computer-controlled scanning system directs the focused laser beam throughout a three-dimensional pattern to produce an incision…. The location of the tissue photodisruption is controlled by moving the focus of the laser beam to the desired surgical target location." Upon information and belief, the LenSx is indicated for use in the creation of an anterior capsulotomy and laser phacofragmentation during cataract surgery. Upon information and belief, the LenSx has a 50 kHz repetition rate for cataract surgery. Upon information and belief, the LenSx has a maximum pulse energy of 15 microjoules for cataract surgery.

118. Alcon's manufacture, use, offer to sell, and sale of the LenSx in the United States has infringed and continues to infringe the '084 patent under 35 U.S.C. § 271(a).

119. Alcon's customers in the United States have directly infringed and continue to directly infringe the '084 patent by using the LenSx for its FDA-approved indications (including anterior capsulotomy and laser phacofragmentation).

120. Alcon has actively induced and continues to actively induce infringement of the '084 patent by encouraging its customers to use the LenSx, with specific intent, knowledge and/or willful blindness that the induced acts constitute patent infringement, in violation of 35 U.S.C.

§ 271(b). Upon information and belief, Alcon's inducing acts include marketing the LenSx, supporting the ongoing use of the LenSx by providing consumables such as the LenSx SoftFit Patient Interface for use with the LenSx, and providing installation, maintenance, service, and/or repair of the LenSx. Alcon has stated that the "LenSx® Laser requires use of proprietary sterile disposable Patient Interfaces." Alcon has further stated "[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system." Alcon's inducing acts also include providing instructions to use the LenSx for its FDA-approved indications (including anterior capsulotomy and laser phacofragmentation) in an infringing manner, including providing the information relevant to each of the claim limitations that is referenced and/or quoted in the paragraphs above. Additionally, upon information and belief, Alcon publishes and provides product documentation and educational materials that instruct and encourage its customers to use the LenSx for its FDA-approved indications in an infringing manner, with knowledge and/or with willful blindness that the induced acts constitute patent infringement. Moreover, upon information and belief, Alcon warns customers in the Operator's Manual for the LenSx that its "instructions must be observed."

121. Alcon has known of the '084 patent and of its infringement prior to this litigation, and it is further on notice through this lawsuit. Alcon's knowledge of the '084 patent, together with its knowledge about the design and operation of the LenSx, gave Alcon knowledge that its customers' use of the LenSx constitutes patent infringement, because the language of the '084 patent claims plainly reads upon the LenSx. Alcon's knowledge of infringement is also demonstrated by its receipt of correspondence and infringement charts specifically identifying its infringing acts, the allegations contained in the original complaint, its prior knowledge of the patent and the subject matter claimed, its statements touting the advantages of features that it knew

to be patented, and the affirmative measures it took to address its risk of liability for patent infringement. Alcon's specific intent to induce infringement is demonstrated by its continued infringing acts despite this knowledge.

122. Alcon has contributed to and continues to contribute to infringement of the '084 patent by offering to sell and selling the LenSx that its customers use to infringe the patent, in violation of 35 U.S.C. § 271(c). Alcon does so knowing that the LenSx constitutes a material part of the invention, and that it is especially made and especially adapted for use in an infringement of the patent. The LenSx is designed and configured so that the customer will use the system to perform FDA-approved anterior capsulotomy and lens fragmentation in a manner that infringes the patent, including as set forth limitation-by-limitation in the paragraphs above. The customer necessarily infringes the patent when it uses the LenSx for the FDA-approved indicated uses of anterior capsulotomy and laser phacofragmentation during cataract surgery. The LenSx includes separate and distinct modes of operation, the "Capsule" and "Lens" Programs, that perform anterior capsulotomy and laser phacofragmentation in an infringing manner, and for which there is no substantial noninfringing use. Using the LenSx for the FDA-approved indications of anterior capsulotomy and laser phacofragmentation during cataract surgery is not a staple article or commodity of commerce, and does not have a substantial noninfringing use. Upon information and belief, customers have no practical ability to modify or use the LenSx for the indicated uses of anterior capsulotomy and laser phacofragmentation in a way to avoid infringement of the '084 patent.

123. Alcon has infringed and continues to infringe the '084 patent by supplying or causing to be supplied in or from the United States, without authority, all or a substantial portion of the components of the patented invention, including but not limited to the LenSx (in either

assembled or unassembled form), parts and software for the LenSx, and consumables such as the LenSx SoftFit Patient Interface, where such components are uncombined in whole or in part, in such a manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, in violation of 35 U.S.C. § 271(f)(1). The components include but are not limited to the hardware and software components that are used to enable and perform the "Capsule" and "Lens" Programs that perform the FDA-approved anterior capsulotomy and laser phacofragmentation in an infringing manner. Alcon's inducing acts include instructions on assembly and use of the LenSx and consumables for use with the LenSx, marketing the LenSx, and providing installation, maintenance, service, and/or repair of the LenSx. Alcon has stated that the "LenSx® Laser requires use of proprietary sterile disposable Patient Interfaces." Alcon has further stated "[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system." Additionally, upon information and belief, Alcon publishes and provides product documentation and educational materials that instruct and encourage its customers to use the LenSx for its FDA-approved indications and in an infringing manner, including providing the information relevant to each of the claim limitations that is referenced and/or quoted in the paragraphs above, with knowledge and/or with willful blindness that the induced acts constitute patent infringement.

124. Alcon has infringed and continues to infringe the '084 patent by supplying or causing to be supplied in or from the United States, without authority, at least one component of the patented invention, including but not limited to the LenSx (in either assembled or unassembled form), and parts and software for the LenSx, that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial

noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component(s) will be combined outside of the United States in a manner that infringe the patent if such combination occurred within the United States, in violation of 35 U.S.C. § 271(f)(2). The components include but are not limited to the hardware and software components that are used to enable and perform the "Capsule" and "Lens" Programs that perform the FDA-approved anterior capsulotomy and laser phacofragmentation in an infringing manner, including as set forth limitation-by-limitation in the paragraphs above, and for which there are no substantial noninfringing uses. Using the LenSx for the FDA-approved indicated uses of anterior capsulotomy and laser phacofragmentation during cataract surgery is not a staple article or commodity of commerce, and does not have a substantial noninfringing use. Upon information and belief, customers have no practical ability to modify or use the LenSx or the components thereto for the indicated uses of anterior capsulotomy and laser phacofragmentation in a way to avoid infringement of the '084 patent.

125. Alcon is not licensed under the '084 patent.

126. The marking requirement of 35 U.S.C. § 287(a) has been satisfied through J&J Surgical Vision's marking of the Catalys® Precision Laser System.

127. J&J Surgical Vision has been damaged and will continue to be damaged by Alcon's infringement of the '084 patent.

128. J&J Surgical Vision has suffered and will continue to suffer irreparable harm unless and until Alcon's infringing activities are enjoined by this Court. J&J Surgical Vision does not have an adequate remedy at law.

129. Despite Alcon's knowledge of the '084 patent and of its infringing activities, Alcon has continued to manufacture, use, offer to sell, and/or sell the LenSx. Alcon's infringement of the

'084 patent has been willful, making this an exceptional case and entitling J&J Surgical Vision to an award of increased damages and attorneys' fees.

COUNT II
Infringement of the '921 Patent

130. J&J Surgical Vision incorporates by reference the allegations set forth in paragraphs 1 through 129 as though fully set forth herein.

131. Alcon has directly and indirectly infringed, and continues to infringe, literally or under the doctrine of equivalents, one or more claims of the '921 patent, by making, using, offering to sell, and/or selling the LenSx and consumables in the United States, and supplying or causing to be supplied the LenSx and consumables from the United States for use abroad, without authority or license, in violation of 35 U.S.C. § 271.

132. For example, the LenSx meets each limitation of claim 1 of the '921 patent, which claims:

> A system for cataract surgery on an eye of a patient, comprising:
>
> > a laser assembly for generating a pulsed laser treatment beam that creates dielectric breakdown in a focal zone of the treatment beam within tissues of the patient's eye so as to effect a cataract surgery procedure;
> >
> > an optical coherence tomography (OCT) 3-Dimensional imaging system configured for imaging tissue of a cataractous crystalline lens of the patient;
> >
> > an optical scanning system configured for positioning the focal zone of the treatment beam to targeted locations of the crystalline lens; and
> >
> > a computer control system operatively coupled to the laser assembly, the imaging system, and the optical scanning system, and programmed to automatically:
> >
> > > a) acquire image data from locations distributed throughout a volume of the cataractous crystalline lens using the imaging system;

b) construct one or more images of the patient's eye tissues from the image data, comprising an image of at least a portion of the crystalline lens;

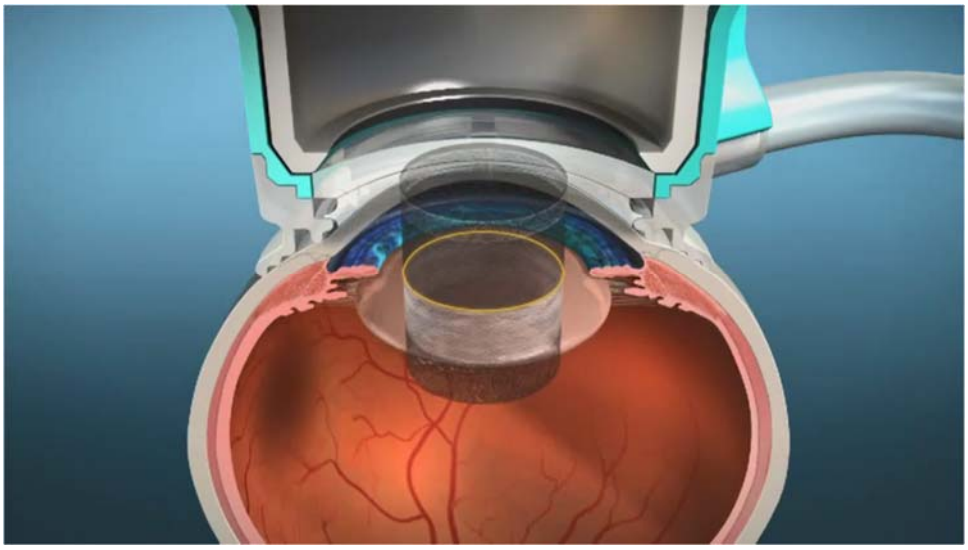
c) construct an anterior capsulotomy cutting region based on the image data, the capsulotomy cutting region comprising an anterior cutting boundary axially spaced from a posterior cutting boundary so as to define an axially-elongated cutting zone transecting the anterior capsule; and

d) operate the optical scanning system and laser assembly to direct a treatment beam in a pattern based on the anterior capsulotomy cutting region so as to create an anterior capsulotomy in the crystalline lens.

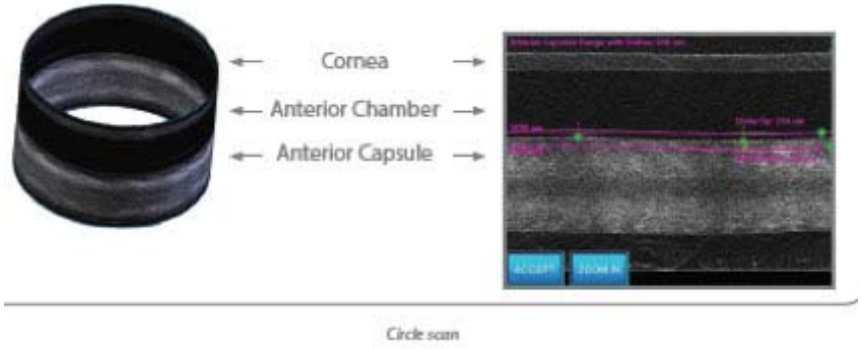
133. The LenSx is a system for cataract surgery on an eye of a patient. For example, Alcon has stated that the LenSx is "indicated for use in patients undergoing cataract surgery." Upon information and belief, the LenSx is designed and indicated for use in the creation of an anterior capsulotomy and laser phacofragmentation during cataract surgery.

134. The LenSx includes a laser assembly for generating a pulsed laser treatment beam that creates dielectric breakdown in a focal zone of the treatment beam within tissues of the patient's eye so as to effect a cataract surgery procedure. For example, Alcon has stated that the LenSx has "an ophthalmic surgical laser which uses focused femtosecond laser pulses to create incisions and to separate tissue within the lens capsule, crystalline lens, and the cornea. A femtosecond light pulse[] is focused into a sufficiently small spot in order to achieve photodisruption of the tissue inside the focus. A tiny volume of tissue, a few microns in diameter, is thereby photodisrupted at the laser focus. A computer-controlled scanning system directs the focused laser beam throughout a three-dimensional pattern to produce an incision." Upon information and belief, the photodisruption is achieved through dielectric breakdown within the tissue structures. Upon information and belief, the LenSx is designed and indicated for use in the creation of an anterior capsulotomy and laser phacofragmentation during cataract surgery.

135. The LenSx includes an optical coherence tomography (OCT) 3-Dimensional imaging system configured for imaging tissue of a cataractous crystalline lens of the patient. Upon information and belief, the LenSx uses a 3D spectral domain OCT imaging assembly. Upon information and belief, the LenSx uses its OCT imaging assembly to generate what Alcon refers to as a circle scan. Alcon has illustrated a circle scan as follows:



The circle scan provides an image of the cataractous crystalline lens. For example, the depth profile is shown in the following diagram that Alcon uses to describe the circle scan:

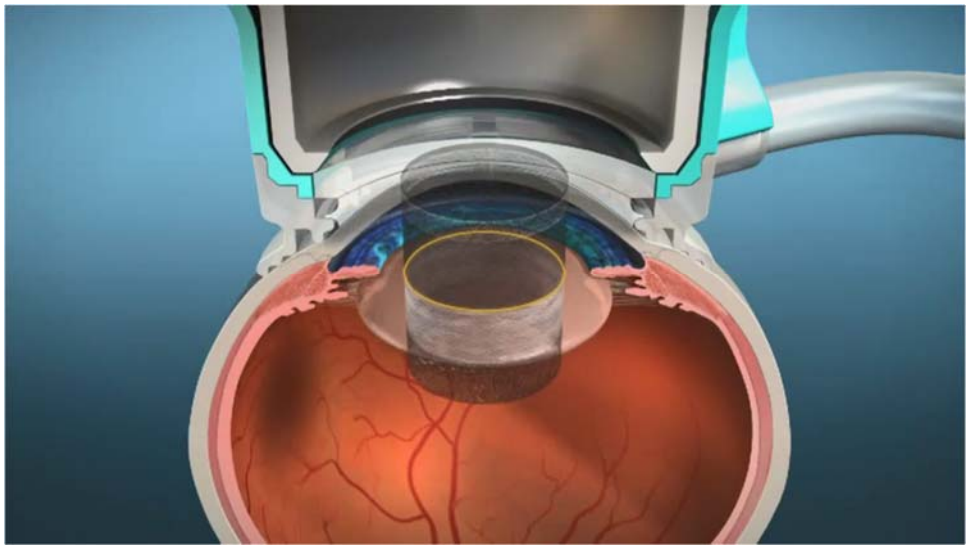


136. The LenSx includes an optical scanning system configured for positioning the focal zone of the treatment beam to targeted locations of the crystalline lens. For example, Alcon has stated that the LenSx has "an ophthalmic surgical laser which uses focused femtosecond laser

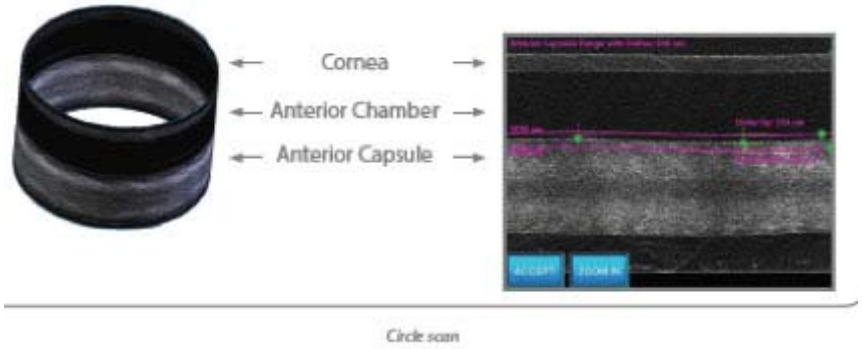
pulses to create incisions and to separate tissue within the lens capsule, crystalline lens, and the cornea. A femtosecond light pulse[] is focused into a sufficiently small spot in order to achieve photodisruption of the tissue inside the focus. A tiny volume of tissue, a few microns in diameter, is thereby photodisrupted at the laser focus. A computer-controlled scanning system directs the focused laser beam throughout a three-dimensional pattern to produce an incision."

137. The LenSx includes a computer control system operatively coupled to the laser assembly, the imaging system, and the optical scanning system, and programmed to automatically acquire image data from locations distributed throughout a volume of the cataractous crystalline lens using the imaging system. For example, Alcon has stated that in the LenSx, "[a] computer monitors and controls the beam energy, repetition rate, safety shutters, footswitch, laser diagnostics, the position of the scanners and the position of the scanning objective lens." Upon information and belief, the LenSx uses a 3D spectral domain OCT imaging assembly. Alcon has stated that its OCT imaging assembly is "a low power visible wavelength light source that is scanned throughout the transparent structures of the anterior chamber of the eye."

138. The LenSx includes a computer control system operatively coupled to the laser assembly, the imaging system, and the optical scanning system, and programmed to automatically construct one or more images of the patient's eye tissues from the image data, comprising an image of at least a portion of the crystalline lens. For example, Alcon has stated that in the LenSx, "[a] computer monitors and controls the beam energy, repetition rate, safety shutters, footswitch, laser diagnostics, the position of the scanners and the position of the scanning objective lens." Upon information and belief the LenSx uses its OCT imaging assembly to generate what Alcon refers to as a circle scan. For example, Alcon has illustrated a circle scan as follows:



The circle scan provides an image of at least a portion of the cataractous crystalline lens. For example, Alcon uses the following diagram to describe the circle scan:



139. The LenSx includes a computer control system operatively coupled to the laser assembly, the imaging system, and the optical scanning system, and programmed to automatically construct an anterior capsulotomy cutting region based on the image data, the capsulotomy cutting region comprising an anterior cutting boundary axially spaced from a posterior cutting boundary so as to define an axially-elongated cutting zone transecting the anterior capsule. For example, Alcon has stated that the LenSx "includes an optical coherence tomography (OCT) based imaging device that assists in localizing specific target locations." Alcon has also stated that "[a]nterior capsulotomy patterns are programmed to cut from at least 100 microns below to 100 microns above

the anterior capsule." Alcon has described the anterior capsulotomy pattern as a "treatment pattern" that "begins as a scanned circle located below the depth of the anterior capsule. Once a scanned circle is completed, a new circle is scanned a few microns above the first circle. As each circle is completed, a cylindrical incision is created. The pattern is automatically completed when the anterior extent of the incision is reached." Upon information and belief, a completed anterior capsulotomy transects the anterior capsule.

140. The LenSx includes a computer control system operatively coupled to the laser assembly, the imaging system, and the optical scanning system, and programmed to automatically operate the optical scanning system and laser assembly to direct a treatment beam in a pattern based on the anterior capsulotomy cutting region so as to create an anterior capsulotomy in the crystalline lens. For example, Alcon has stated that in the LenSx, "a computer-controlled scanning system directs the laser beam throughout a three-dimensional pattern to produce an incision…. The location of the tissue photodisruption is controlled by moving the focus of the laser beam to the desired surgical target location." Upon information and belief, the LenSx is indicated for use in the creation of an anterior capsulotomy. Alcon has stated that "[a]nterior capsulotomy patterns are programmed to cut from at least 100 microns below to 100 microns above the anterior capsule." Alcon has described the anterior capsulotomy pattern as a "treatment pattern" that "begins as a scanned circle located below the depth of the anterior capsule. Once a scanned circle is completed, a new circle is scanned a few microns above the first circle. As each circle is completed, a cylindrical incision is created. The pattern is automatically completed when the anterior extent of the incision is reached."

141. Alcon's manufacture, use, offer to sell, and sale of the LenSx in the United States has infringed and continues to infringe the '921 patent under 35 U.S.C. § 271(a).

142. Alcon's customers in the United States have directly infringed and continue to directly infringe the '921 patent by using the LenSx for its FDA-approved indications (including anterior capsulotomy and laser phacofragmentation).

143. Alcon has actively induced and continues to actively induce infringement of the '921 patent by encouraging its customers to use the LenSx, with specific intent, knowledge and/or willful blindness that the induced acts constitute patent infringement, in violation of 35 U.S.C. § 271(b). Upon information and belief, Alcon's inducing acts include marketing the LenSx, supporting the ongoing use of the LenSx by providing consumables such as the LenSx SoftFit Patient Interface for use with the LenSx, and providing installation, maintenance, service, and/or repair of the LenSx. Alcon has stated that the "LenSx® Laser requires use of proprietary sterile disposable Patient Interfaces." Alcon has further stated "[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system." Alcon's inducing acts also include providing instructions to use the LenSx for its FDA-approved indications (including anterior capsulotomy and laser phacofragmentation) in an infringing manner, including providing the information relevant to each of the claim limitations that is referenced and/or quoted in the paragraphs above. Additionally, upon information and belief, Alcon has published and provided product documentation and educational materials that instruct and encourage its customers to use the LenSx for its FDA-approved indications in an infringing manner. Moreover, upon information and belief, Alcon warns customers in the Operator's Manual for the LenSx that its "instructions must be observed."

144. Alcon has known of the '921 patent and of its infringement prior to this litigation, and it is further on notice through this lawsuit. Alcon's knowledge of the '921 patent, together with its knowledge about the design and operation of the LenSx, gave Alcon knowledge that its

customers' use of the LenSx constitutes patent infringement, because the language of the '921 patent claims plainly reads upon the LenSx. Alcon's knowledge of infringement is also demonstrated by its receipt of correspondence and infringement charts specifically identifying its infringing acts, the allegations contained in the original complaint, its prior knowledge of the patent and the subject matter claimed, its statements touting the advantages of features that it knew to be patented, and the affirmative measures it took to address its risk of liability for patent infringement. Alcon's specific intent to induce infringement is demonstrated by its continued infringing acts despite this knowledge.

145. Alcon has contributed to and continues to contribute to infringement of the '921 patent by offering to sell and selling the LenSx that its customers use to infringe the patent, in violation of 35 U.S.C. § 271(c). Alcon does so knowing that the LenSx constitutes a material part of the invention, and that it is especially made and especially adapted for use in an infringement of the patent. The LenSx is designed and configured so that the customer will use the system to perform FDA-approved anterior capsulotomy and lens fragmentation in a manner that infringes the patent, including as set forth limitation-by-limitation in the paragraphs above. The customer necessarily infringes the patent when it uses the LenSx for the FDA-approved indicated uses of anterior capsulotomy and laser phacofragmentation during cataract surgery. The LenSx includes separate and distinct modes of operation, the "Capsule" and "Lens" Programs, that perform anterior capsulotomy and laser phacofragmentation in an infringing manner, and for which there is no substantial noninfringing use. Using the LenSx for the FDA-approved indications of anterior capsulotomy and laser phacofragmentation during cataract surgery is a not staple article or commodity of commerce, and does not have a substantial noninfringing use. Upon information and belief, customers have no practical ability to modify or use the LenSx for the indicated uses

of anterior capsulotomy and laser phacofragmentation in a way to avoid infringement of the '921 patent.

146. Alcon has infringed and continues to infringe the '921 patent by supplying or causing to be supplied in or from the United States, without authority, all or a substantial portion of the components of the patented invention, including but not limited to the LenSx (in either assembled or unassembled form), parts and software of the LenSx, and consumables such as the LenSx SoftFit Patient Interface, where such components are uncombined in whole or in part, in such a manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, in violation of 35 U.S.C. § 271(f)(1). The components include but are not limited to the hardware and software components that are used to enable and perform the "Capsule" and "Lens" Programs that perform the FDA-approved anterior capsulotomy and laser phacofragmentation in an infringing manner. Alcon's inducing acts include instructions on assembly and use of the LenSx and consumables for use with the LenSx, marketing the LenSx, and providing installation, maintenance, service, and/or repair of the LenSx. Alcon has stated that the "LenSx® Laser requires use of proprietary sterile disposable Patient Interfaces." Alcon has further stated "[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system." Additionally, upon information and belief, Alcon publishes and provides product documentation and educational materials that instruct and encourage its customers to use the LenSx for its FDA-approved indications and in an infringing manner, including providing the information relevant to each of the claim limitations that is referenced and/or quoted in the paragraphs above, with knowledge and/or with willful blindness that the induced acts constitute patent infringement.

147. Alcon has infringed and continues to infringe the '921 patent by supplying or causing to be supplied in or from the United States, without authority, at least one component of the patented invention, including but not limited to the LenSx (in either assembled or unassembled form), and parts and software for the LenSx, that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component(s) will be combined outside of the United States in a manner that infringe the patent if such combination occurred within the United States, in violation of 35 U.S.C. § 271(f)(2). The components include but are not limited to the hardware and software components that are used to enable and perform the "Capsule" and "Lens" Programs that perform the FDA-approved anterior capsulotomy and laser phacofragmentation in an infringing manner, including as set forth limitation-by-limitation in the paragraphs above, and for which there are no substantial noninfringing uses. Using the LenSx for the FDA-approved indicated uses of anterior capsulotomy and laser phacofragmentation during cataract surgery is not a staple article or commodity of commerce, and does not have a substantial noninfringing use. Upon information and belief, customers have no practical ability to modify or use the LenSx or the components thereto for the indicated uses of anterior capsulotomy and laser phacofragmentation in a way to avoid infringement of the '921 patent.

148. Alcon is not licensed under the '921 patent.

149. The marking requirement of 35 U.S.C. § 287(a) has been satisfied through J&J Surgical Vision's marking of the Catalys® Precision Laser System.

150. J&J Surgical Vision has been damaged and will continue to be damaged by Alcon's infringement of the '921 patent.

151. J&J Surgical Vision has suffered and will continue to suffer irreparable harm unless and until Alcon's infringing activities are enjoined by this Court. J&J Surgical Vision does not have an adequate remedy at law.

152. Despite Alcon's knowledge of the '921 patent and of its infringing activities, Alcon has continued to manufacture, use, offer to sell, and/or sell the LenSx. Alcon's infringement of the '921 patent has been willful, making this an exceptional case and entitling J&J Surgical Vision to an award of increased damages and attorneys' fees.

COUNT III
Infringement of the '497 Patent

153. J&J Surgical Vision incorporates by reference the allegations set forth in paragraphs 1 through 152 as though fully set forth herein.

154. Alcon has directly and indirectly infringed, and continues to infringe, literally or under the doctrine of equivalents, one or more claims of the '497 patent, by making, using, offering to sell, and/or selling the LenSx and consumables in the United States, without authority or license, in violation of 35 U.S.C. § 271.

155. For example, the LenSx meets each limitation of at least claim 1 of the '497 patent, which claims:

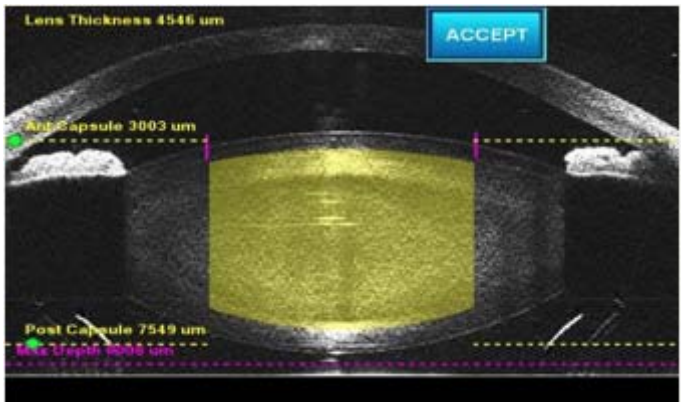
> A method of making an incision in eye tissue during a cataract surgical procedure, the method comprising:
>
> > operating an imaging system, coupled to an electronics control system comprising a computer, so as to acquire image data from locations distributed throughout a volume of a crystalline lens of a patient and construct one or more images of the patient's eye tissues from the image data, wherein the one or more images include an image of at least a portion of the crystalline lens;
> >
> > identifying, using the control system, a cutting region based on the image data, the cutting region being at least partially defined by an anterior cutting boundary and a posterior cutting boundary and including a portion of the crystalline lens;

> generating a beam of light using a pulsed laser system guided by the control system so as to scan the beam in a pattern within the cutting region and segment the crystalline lens into a plurality of pieces for subsequent removal, the segmentation of the crystalline lens including:
>
> > focusing the beam at a first focal point located at a first depth in the eye tissue;
> >
> > scanning the beam on the eye while focused at the first depth so as to create an incision pattern within the cutting region at the first depth;
> >
> > focusing the beam at a second focal point located at a second depth in the eye tissue different than the first depth; and
> >
> > scanning the beam on the eye while focused at the second depth so as to create an incision pattern within the cutting region at the second depth.

156. The LenSx practices a method of making an incision in eye tissue during a cataract surgical procedure. Upon information and belief, the LenSx is designed and indicated for use in the creation of an anterior capsulotomy and laser phacofragmentation during cataract surgery.

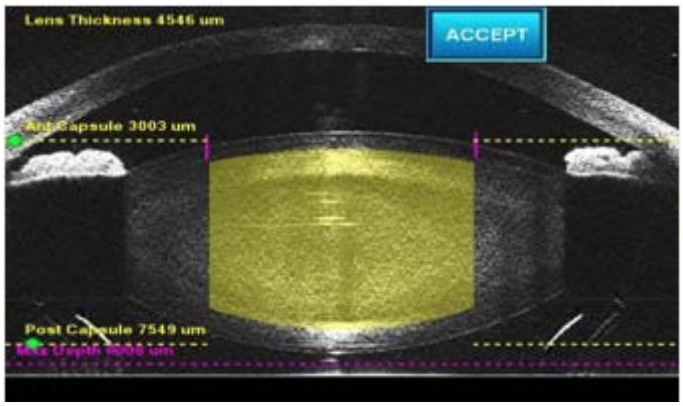
157. The LenSx operates an imaging system, coupled to an electronics control system comprising a computer, so as to acquire image data from locations distributed throughout a volume of a crystalline lens of a patient and construct one or more images of the patient's eye tissues from the image data, wherein the one or more images include an image of at least a portion of the crystalline lens. For example, Alcon has stated that in the LenSx, "[a] computer monitors and controls the beam energy, repetition rate, safety shutters, footswitch, laser diagnostics, the position of the scanners and the position of the scanning objective lens." Upon information and belief, the LenSx uses a 3D spectral domain OCT imaging assembly. Alcon has stated that its OCT imaging assembly is "a low power visible wavelength light source that is scanned throughout the transparent structures of the anterior chamber of the eye." For example, upon information and

belief the LenSx uses its OCT imaging assembly to generate what Alcon refers to as a line scan. For example, Alcon has shown an image of a line scan as follows:



The line scan provides an image of at least a portion of the crystalline lens.

158. The LenSx identifies, using the control system, a cutting region based on the image data, the cutting region being at least partially defined by an anterior cutting boundary and a posterior cutting boundary and including a portion of the crystalline lens. For example, Alcon has stated that the LenSx "includes an optical coherence tomography (OCT) based imaging device that assists in localizing specific target locations." For example, Alcon has shown an image of the target locations as follows:



Alcon has stated that "[t]he Lens treatment volume is represented by a yellow semi-transparent solid. The upper arc of the solid matches the programmed Anterior Lens Curvature and

the lower arc corresponds to the programmed Posterior Lens Curvature." Upon information and belief the treatment volume includes at least a portion of the crystalline lens.

159. The LenSx generates a beam of light using a pulsed laser system guided by the control system so as to scan the beam in a pattern within the cutting region and segment the crystalline lens into a plurality of pieces for subsequent removal, the segmentation of the crystalline lens including focusing the beam at a first focal point located at a first depth in the eye tissue. For example, Alcon has stated that the LenSx has "an ophthalmic surgical laser which uses focused femtosecond laser pulses to create incisions and to separate tissue within the lens capsule, crystalline lens, and the cornea." Alcon has also stated that in the LenSx, "[a] computer monitors and controls the beam energy, repetition rate, safety shutters, footswitch, laser diagnostics, the position of the scanners and the position of the scanning objective lens." Alcon has stated that the resulting "Lens Pattern is used to perform phacofragmentation of the crystalline lens. Lens Patterns may be specified as Chop, Cylinder or combined Chop and Cylinder patterns." Alcon has also stated that these "[l]ens phacofragmentation patterns are programmed to cut from at least 500 microns above the posterior capsule to at least 500 microns below the anterior capsule." Upon information and belief, phacofragmentation segments the lens into a plurality of pieces for subsequent removal. Alcon has stated that the phacofragmentation "treatment pattern begins at the programmed posterior depth."

160. The LenSx generates a beam of light using a pulsed laser system guided by the control system so as to scan the beam in a pattern within the cutting region and segment the crystalline lens into a plurality of pieces for subsequent removal, the segmentation of the crystalline lens including scanning the beam on the eye while focused at the first depth so as to create an incision pattern within the cutting region at the first depth. For example, Alcon has stated

that the phacofragmentation "treatment pattern begins at the programmed posterior depth as an initial x-shaped scan is complete."

161. The LenSx generates a beam of light using a pulsed laser system guided by the control system so as to scan the beam in a pattern within the cutting region and segment the crystalline lens into a plurality of pieces for subsequent removal, the segmentation of the crystalline lens including focusing the beam at the second focal point located at a second depth in the eye tissue different than the first depth. For example, Alcon has stated that the incision of the treatment pattern at the programmed posterior depth is "followed by successive x-shaped scans created a few microns apart." Alcon has also stated that these "cuts proceed from the deepest point and move anteriorly, ending below the anterior capsule."

162. The LenSx generates a beam of light using a pulsed laser system guided by the control system so as to scan the beam in a pattern within the cutting region and segment the crystalline lens into a plurality of pieces for subsequent removal, the segmentation of the crystalline lens including scanning the beam on the eye while focused at the second depth so as to create an incision pattern within the cutting region at the second depth. For example, Alcon has stated that the incision of the treatment pattern at the programmed posterior depth is "followed by successive x-shaped scans created a few microns apart." Alcon has also stated that these "cuts proceed from the deepest point and move anteriorly, ending below the anterior capsule."

163. Alcon's use of the LenSx in the United States has infringed and continues to infringe the '497 patent under 35 U.S.C. § 271(a).

164. Alcon's customers in the United States have directly infringed and continue to directly infringe the '497 patent by using the LenSx for its FDA-approved indications (including laser phacofragmentation).

165. Alcon has actively induced and continues to actively induce infringement of the '497 patent by encouraging its customers to use the LenSx, with specific intent, knowledge and/or willful blindness that the induced acts constitute patent infringement, in violation of 35 U.S.C. § 271(b). Upon information and belief, Alcon's inducing acts include marketing the LenSx, supporting the ongoing use of the LenSx by providing consumables such as the LenSx SoftFit Patient Interface for use with the LenSx, and providing installation, maintenance, service, and/or repair of the LenSx. Alcon has stated that the "LenSx® Laser requires use of proprietary sterile disposable Patient Interfaces." Alcon has further stated "[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system." Alcon's inducing acts also include providing instructions to use the LenSx for its FDA-approved indications (including laser phacofragmentation) in an infringing manner, including providing the information relevant to each of the claim limitations that is referenced and/or quoted in the paragraphs above. Additionally, upon information and belief, Alcon has published and provided product documentation and educational materials that instruct and encourage its customers to use the LenSx for its FDA-approved indications in an infringing manner, with knowledge and/or with willful blindness that the induced acts constitute patent infringement. Moreover, upon information and belief, Alcon warns customers in the Operator's Manual for the LenSx that its "instructions must be observed."

166. Alcon has known of the '497 patent and of its infringement prior to this litigation, and it is further on notice through this lawsuit. Alcon's knowledge of the '497 patent, together with its knowledge about the design and operation of the LenSx, gave Alcon knowledge that its customers' use of the LenSx constitutes patent infringement, because the language of the '497 patent claims plainly reads upon the LenSx. Alcon's knowledge of infringement is also

demonstrated by its receipt of correspondence and infringement charts specifically identifying its infringing acts, the allegations contained in the original complaint, its prior knowledge of the patent and the subject matter claimed, its statements touting the advantages of features that it knew to be patented, and the affirmative measures it took to address its risk of liability for patent infringement. Alcon's specific intent to induce infringement is demonstrated by its continued infringing acts despite this knowledge.

167. Alcon has contributed to and continues to contribute to infringement of the '497 patent by offering to sell and selling the LenSx that its customers use to infringe the patent, in violation of 35 U.S.C. § 271(c). Alcon does so knowing that the LenSx constitutes a material part of the invention, and that it is especially made and especially adapted for use in an infringement of the patent. The LenSx is designed and configured so that the customer will use the system to perform FDA-approved lens fragmentation in a manner that infringes the patent, including as set forth limitation-by-limitation in the paragraphs above. The customer necessarily infringes the patent when it uses the LenSx for the FDA-approved indicated use of laser phacofragmentation during cataract surgery. The LenSx includes a separate and distinct mode of operation, the "Lens" Program, that performs laser phacofragmentation in an infringing manner, and for which there is no substantial noninfringing use. Using the LenSx for the FDA-approved indication of laser phacofragmentation during cataract surgery is not a staple article or commodity of commerce, and does not have a substantial noninfringing use. Upon information and belief, customers have no practical ability to modify or use the LenSx for the indicated use of laser phacofragmentation in a way to avoid infringement of the '497 patent.

168. Alcon is not licensed under the '497 patent.

169. J&J Surgical Vision has been damaged and will continue to be damaged by Alcon's infringement of the '497 patent.

170. J&J Surgical Vision has suffered and will continue to suffer irreparable harm unless and until Alcon's infringing activities are enjoined by this Court. J&J Surgical Vision does not have an adequate remedy at law.

171. Despite Alcon's knowledge of the '497 patent and of its infringing activities, Alcon has continued to manufacture, use, offer to sell, and/or sell the LenSx. Alcon's infringement of the '497 patent has been willful, making this an exceptional case and entitling J&J Surgical Vision to an award of increased damages and attorneys' fees.

COUNT IV
Infringement of the '724 Patent

172. J&J Surgical Vision incorporates by reference the allegations set forth in paragraphs 1 through 171 as though fully set forth herein.

173. Alcon has directly and indirectly infringed, and continues to infringe, literally or under the doctrine of equivalents, one or more claims of the '724 patent, by making, using, offering to sell, and/or selling the LenSx and consumables in the United States, without authority or license, in violation of 35 U.S.C. § 271.

174. For example, the LenSx meets each limitation of at least Claim 1 of the '724 patent, which claims:

> A method for laser cataract surgery that protects the retina of the eye from laser exposure, comprising:
>
> a. generating, using a computer, an image of at least a portion of a crystalline lens of the eye based on detecting remitted light from locations distributed throughout a volume of the crystalline lens;
>
> b. processing data including the image data so as to determine a targeted treatment region in the lens of the eye, wherein the targeted treatment region comprises an axially-elongated cutting zone

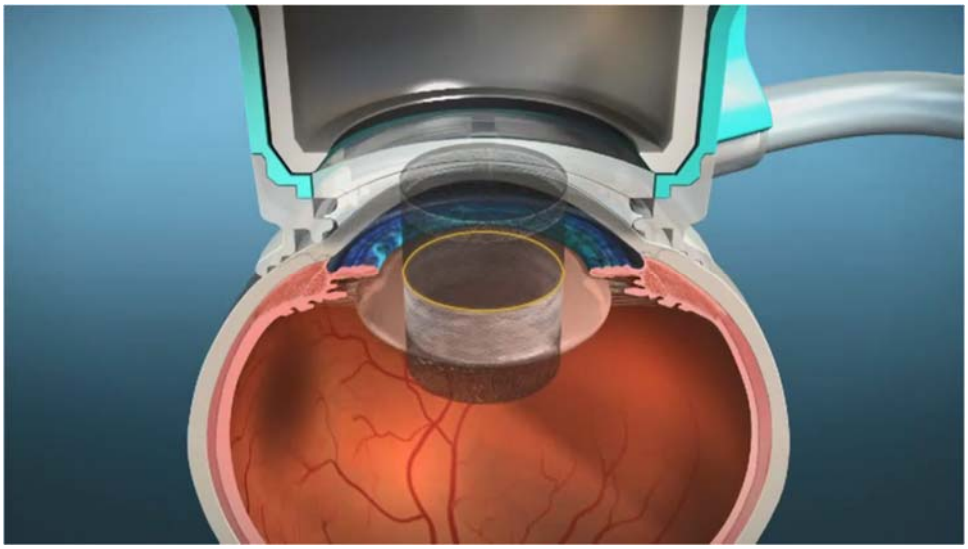
transecting the anterior capsule and does not transect the posterior capsule of the lens;

c. directing a laser beam, under computer guided control, in a first pattern to photodisrupt at least a portion of lens tissue of the eye to create a light scattering region; and

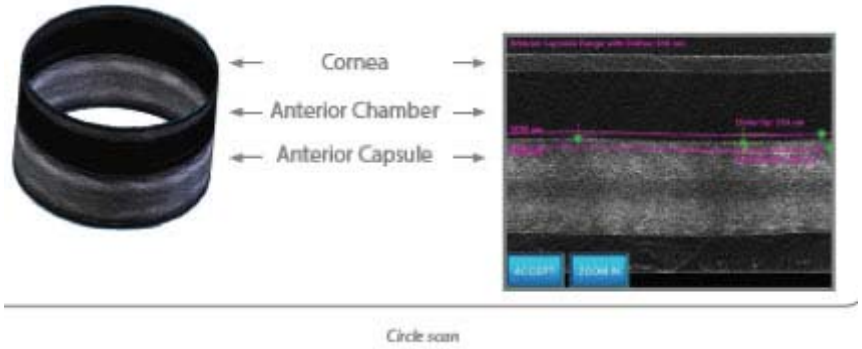
d. subsequently directing the laser beam, under computer guided control, in a second pattern in lens tissue anterior to the light scattering region so as to photodisrupt at least a portion of the targeted region, thereby effecting patterned laser cutting of lens tissue for subsequent removal of pieces or segments of lens tissue.

175. The LenSx practices a method for laser cataract surgery that protects the retina of the eye from laser exposure. For example, Alcon has stated that the LenSx is designed and "indicated for use in patients undergoing cataract surgery … the LenSx® Laser creates incisions through tightly focused femtosecond laser pulses that cut tissue with micron-scale precision." Upon information and belief, these laser pulses are directed in a manner to avoid damage to the retina of the eye.

176. The LenSx generates using a computer, an image of at least a portion of a crystalline lens of the eye based on detecting remitted light from locations distributed throughout a volume of the crystalline lens. Upon information and belief, the LenSx uses its OCT imaging assembly to generate what Alcon refers to as a circle scan. For example, Alcon has illustrated a circle scan as follows:



The circle scan provides an image at least a portion of the crystalline lens. For example, Alcon has shown an image of a circle scan as follows:



Upon information and belief, the LenSx uses a 3D spectral domain OCT imaging assembly to generate the circle scan. For example, Alcon has stated that its OCT imaging assembly is "a low power visible wavelength light source that is scanned throughout the transparent structures of the anterior chamber of the eye."

177. The LenSx processes data including the image data so as to determine a targeted treatment region in the lens of the eye, wherein the targeted treatment region comprises an axially-elongated cutting zone transecting the anterior capsule and does not transect the posterior capsule of the lens. For example, Alcon has stated that the LenSx "includes an optical coherence

tomography (OCT) based imaging device that assists in localizing specific target locations." Additionally, "[t]he treatment pattern begins as a scanned circle located below the depth of the anterior capsule. Once a scanned circle is completed, a new circle is scanned a few microns above the first circle. As each circle is completed, a cylindrical incision is created." Upon information and belief, the targeted treatment region comprises an axially-elongated cutting zone transecting the anterior capsule and does not transect the posterior capsule of the lens.

178. The LenSx directs a laser beam, under computer guided control, in a first pattern to photodisrupt at least a portion of the lens tissue of the eye to create a light scattering region. For example, Alcon has stated that "[t]he LenSx® Laser System uses focused femtosecond laser pulses … and separates tissue in the … crystalline lens…. Individual photodisruption locations are controlled by repeatedly repositioning the laser focus. The light pulse is focused into a sufficiently small spot in order to achieve photodisruption of the tissue inside the focus. A tiny volume of tissue, a few microns in diameter, is photodisrupted at the laser focus…. The location of the tissue photodisruption is controlled by moving the focus of the laser beam to the desired surgical target location. A computer-controlled scanning system directs the laser beam throughout a three-dimensional pattern to produce an incision."

179. The LenSx subsequently directs the laser beam, under computer guided control, in a second pattern in lens tissue anterior to the light scattering region so as to photodisrupt at least a portion of the targeted region, thereby effecting patterned laser cutting of lens tissue for subsequent removal of pieces or segments of lens tissue. For example, Alcon has stated that the phacofragmentation "treatment pattern begins at the programmed posterior depth as an initial x-shaped scan is complete, followed by successive x-shaped scans created a few microns apart. As each scan is completed, the lateral extent of the scans is adjusted to fill-in the elliptically shaped

volume. The result is two or more vertically oriented, elliptically shaped planes that intersect at the lens center. As an alternative, a number of cylindrical shells may be generated in lieu of the planes or in combination with the planes. The pattern is automatically completed when the programmed anterior depth is reached." Upon information and belief, phacofragmentation segments the lens into a plurality of pieces for subsequent removal.

180. Alcon's use of the LenSx in the United States has infringed and continues to infringe the '724 patent under 35 U.S.C. § 271(a).

181. Alcon's customers in the United States have directly infringed and continue to directly infringe the '724 patent by using the LenSx for its FDA-approved indications (including anterior capsulotomy and laser phacofragmentation).

182. Alcon has actively induced and continues to actively induce infringement of the '724 patent by encouraging its customers to use the LenSx, with specific intent, knowledge and/or willful blindness that the induced acts constitute patent infringement, in violation of 35 U.S.C. § 271(b). Upon information and belief, Alcon's inducing acts include marketing the LenSx, supporting the ongoing use of the LenSx by providing consumables such as the LenSx SoftFit Patient Interface for use with the LenSx, and providing installation, maintenance, service, and/or repair of the LenSx. Alcon has stated that the "LenSx® Laser requires use of proprietary sterile disposable Patient Interfaces." Alcon has further stated "[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system." Alcon's inducing acts also include providing instructions to use the LenSx for its FDA-approved indications (including anterior capsulotomy and laser phacofragmentation) in an infringing manner, including providing the information relevant to each of the claim limitations that is referenced and/or quoted in the paragraphs above. Additionally, upon information and belief, Alcon has published and provided

product documentation and educational materials that instruct and encourage its customers to use the LenSx for its FDA-approved indications in an infringing manner, with knowledge and/or with willful blindness that the induced acts constitute patent infringement. Moreover, upon information and belief, Alcon warns customers in the Operator's Manual for the LenSx that its "instructions must be observed."

183. Alcon has known of the '724 patent and of its infringement prior to this litigation, and it is further on notice through this lawsuit. Alcon's knowledge of the '724 patent, together with its knowledge about the design and operation of the LenSx, gave Alcon knowledge that its customers' use of the LenSx constitutes patent infringement, because the language of the '724 patent claims plainly reads upon the LenSx. Alcon's knowledge of infringement is also demonstrated by its receipt of correspondence and infringement charts specifically identifying its infringing acts, the allegations contained in the original complaint, its prior knowledge of the patent and the subject matter claimed, its statements touting the advantages of features that it knew to be patented, and the affirmative measures it took to address its risk of liability for patent infringement. Alcon's specific intent to induce infringement is demonstrated by its continued infringing acts despite this knowledge.

184. Alcon has contributed to and continues to contribute to infringement of the '724 patent by offering to sell and selling the LenSx that its customers use to infringe the patent, in violation of 35 U.S.C. § 271(c). Alcon does so knowing that the LenSx constitutes a material part of the invention, and that it is especially made and especially adapted for use in an infringement of the patent. The LenSx is designed and configured so that the customer will use the system to perform FDA-approved anterior capsulotomy and lens fragmentation in a manner that infringes the patent, including as set forth limitation-by-limitation in the paragraphs above. The customer

necessarily infringes the patent when it uses the LenSx for the FDA-approved indicated uses of anterior capsulotomy and laser phacofragmentation during cataract surgery. The LenSx includes separate and distinct modes of operation, the "Capsule" and "Lens" Programs, that perform anterior capsulotomy and laser phacofragmentation in an infringing manner, and for which is no substantial noninfringing use. Using the LenSx for the FDA-approved indications of anterior capsulotomy and laser phacofragmentation during cataract surgery is a not a staple article or commodity of commerce, and does not have a substantial noninfringing use. Upon information and belief, customers have no practical ability to modify or use the LenSx for the indicate uses of anterior capsulotomy and laser phacofragmentation in a way to avoid infringement of the '724 patent.

185. Alcon is not licensed under the '724 patent.

186. J&J Surgical Vision has been damaged and will continue to be damaged by Alcon's infringement of the '724 patent.

187. J&J Surgical Vision has suffered and will continue to suffer irreparable harm unless and until Alcon's infringing activities are enjoined by this Court. J&J Surgical Vision does not have an adequate remedy at law.

188. Despite Alcon's knowledge of the '724 patent and of its infringing activities, Alcon has continued to manufacture, use, offer to sell, and/or sell the LenSx. Alcon's infringement of the '724 patent has been willful, making this an exceptional case and entitling J&J Surgical Vision to an award of increased damages and attorneys' fees.

COUNT V
Infringement of the '001 Patent

189. J&J Surgical Vision incorporates by reference the allegations set forth in paragraphs 1 through 188 as though fully set forth herein.

190. Alcon has directly and indirectly infringed, and continues to infringe, literally or under the doctrine of equivalents, one or more claims of the '001 patent, by making, using, offering to sell, and/or selling the LenSx and consumables in the United States, without authority or license, in violation of 35 U.S.C. § 271.

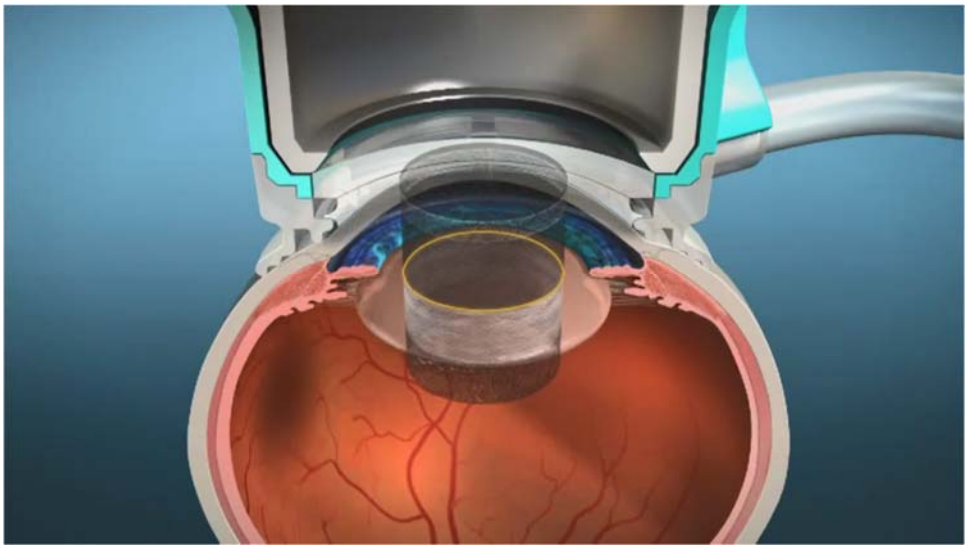
191. For example, the LenSx meets each limitation of at least claim 1 of the '001 patent, which claims:

> A method for cataract surgery on an eye of a patient using a pulsed laser surgical system, comprising:
>
> > operating an imaging system so as to acquire image data from locations distributed throughout a volume of a cataractous crystalline lens of the patient and construct one or more images of the patient's eye tissues from the image data, wherein the one or more images comprise an image of at least a portion of the crystalline lens;
> >
> > constructing, using a computer system, an anterior capsulotomy cutting region based on the image data, the capsulotomy cutting region comprising an anterior cutting boundary axially spaced from a posterior cutting boundary so as to define an axially-elongated cutting zone transecting the anterior capsule; and
> >
> > operating the surgical system to direct a pulsed laser treatment beam in a pattern based on the anterior capsulotomy cutting region so as to create an anterior capsulotomy in the crystalline lens.

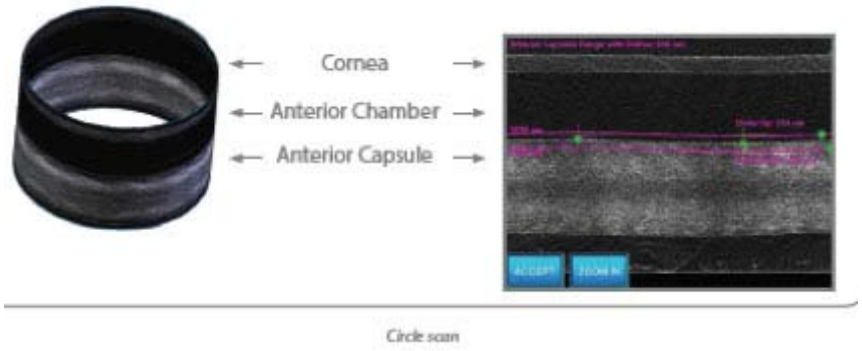
192. The LenSx practices a method for cataract surgery on an eye of a patient using a pulsed laser surgical system. For example, Alcon has stated that "[t]he LenSx® Laser is indicated for use in patients undergoing cataract surgery … The LenSx® Laser creates incisions through tightly focused femtosecond laser pulses that cut tissue with micron-scale precision."

193. The LenSx operates an imaging system so as to acquire image data from locations distributed throughout a volume of a cataractous crystalline lens of the patient and construct one or more images of the patient's eye tissues from the image data, wherein the one or more images comprise an image of at least a portion of the crystalline lens. Upon information and belief, the

LenSx uses a 3D spectral domain OCT imaging assembly. For example, Alcon has stated that its OCT imaging assembly is "a low power visible wavelength light source that is scanned throughout the transparent structures of the anterior chamber of the eye." Upon information and belief, the LenSx uses its OCT imaging assembly to generate what Alcon refers to as a circle scan. Alcon has illustrated a circle scan as follows:



The circle scan provides an image of at least a portion of the cataractous crystalline lens. For example, Alcon has shown an image of a circle scan as follows:



194. The LenSx constructs, using a computer system, an anterior capsulotomy cutting region based on the image data, the capsulotomy cutting region comprising an anterior cutting boundary axially spaced from a posterior cutting boundary so as to define an axially-elongated

cutting zone transecting the anterior capsule. For example, Alcon has stated that the LenSx "includes an optical coherence tomography (OCT) based imaging device that assists in localizing specific target locations." For example, Alcon has stated that in the LenSx, "a computer-controlled scanning system directs the laser beam throughout a three-dimensional pattern to produce an incision…. The location of the tissue photodisruption is controlled by moving the focus of the laser beam to the desired surgical target location." Alcon has stated that "[a]nterior capsulotomy patterns are programmed to cut from at least 100 microns below to 100 microns above the anterior capsule." Alcon has described the anterior capsulotomy pattern as a "treatment pattern" that "begins as a scanned circle located below the depth of the anterior capsule. Once a scanned circle is completed, a new circle is scanned a few microns above the first circle. As each circle is completed, a cylindrical incision is created. The pattern is automatically completed when the anterior extent of the incision is reached." Upon information and belief, a completed anterior capsulotomy transects the anterior capsule.

195. The LenSx operates the surgical system to direct a pulsed laser treatment beam in a pattern based on the anterior capsulotomy cutting region so as to create an anterior capsulotomy in the crystalline lens. For example, Alcon has stated that in the LenSx, "a computer-controlled scanning system directs the laser beam throughout a three-dimensional pattern to produce an incision…. The location of the tissue photodisruption is controlled by moving the focus of the laser beam to the desired surgical target location." Alcon has also stated that the LenSx has "an ophthalmic surgical laser which uses focused femtosecond laser pulses to create incisions." Alcon has stated that "[t]he treatment pattern begins as a scanned circle located below the depth of the anterior capsule. Once a scanned circle is completed, a new circle is scanned a few microns above the first circle. As each circle is completed, a cylindrical incision is created. The pattern is

automatically completed when the anterior extent of the incision is reached." Alcon has also stated that "[t]he Capsule Pattern is used to perform an anterior capsulotomy of the crystalline lens. The anterior capsulotomy is created by scanning a cylindrical shell."

196. Alcon's manufacture, use, offer to sell, and sale of the LenSx in the United States has infringed and continues to infringe the '001 patent under 35 U.S.C. § 271(a).

197. Alcon's customers in the United States have directly infringed and continue to directly infringe the '001 patent by using the LenSx for its FDA-approved indications (including anterior capsulotomy and laser phacofragmentation).

198. Alcon has actively induced and continues to actively induce infringement of the '001 patent by encouraging its customers to use the LenSx, with specific intent, knowledge and/or willful blindness that the induced acts constitute patent infringement, in violation of 35 U.S.C. § 271(b). Upon information and belief, Alcon's inducing acts include marketing the LenSx, supporting the ongoing use of the LenSx by providing consumables such as the LenSx SoftFit Patient Interface for use with the LenSx, and providing installation, maintenance, service, and/or repair of the LenSx. Alcon has stated that the "LenSx® Laser requires use of proprietary sterile disposable Patient Interfaces." Alcon has further stated "[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system." Alcon's inducing acts also include providing instructions to use the LenSx for its FDA-approved indications for use (including anterior capsulotomy and laser phacofragmentation) in an infringing manner, including providing the information relevant to each of the claim limitations that is referenced and/or quoted in the paragraphs above. Additionally, upon information and belief, Alcon has published and provided product documentation and educational materials that instruct and encourage its customers to use the LenSx for its FDA-approved indications in an infringing manner, with

knowledge and/or with willful blindness that the induced acts constitute patent infringement. Moreover, upon information and belief, Alcon warns customers in the Operator's Manual for the LenSx that its "instructions must be observed."

199. Alcon has known of the '001 patent and of its infringement prior to this litigation, and it is further on notice through this lawsuit. Alcon's knowledge of the '001 patent, together with its knowledge about the design and operation of the LenSx, gave Alcon knowledge that its customers' use of the LenSx constitutes patent infringement, because the language of the '001 patent claims plainly reads upon the LenSx. Alcon's knowledge of infringement is also demonstrated by its receipt of correspondence and infringement charts specifically identifying its infringing acts, the allegations contained in the original complaint, its prior knowledge of the patent and the subject matter claimed, its statements touting the advantages of features that it knew to be patented, and the affirmative measures it took to address its risk of liability for patent infringement. Alcon's specific intent to induce infringement is demonstrated by its continued infringing acts despite this knowledge.

200. Alcon has contributed to and continues to contribute to infringement of the '001 patent by offering to sell and selling the LenSx that its customers use to infringe the patent, in violation of 35 U.S.C. § 271(c). Alcon does so knowing that the LenSx constitutes a material part of the invention, and that it is especially made and especially adapted for use in an infringement of the patent. The LenSx is designed and configured so that the customer will use the system to perform FDA-approved anterior capsulotomy and lens fragmentation in a manner that infringes the patent, including as set forth limitation-by-limitation in the paragraphs above. The customer necessarily infringes the patent when it uses the LenSx for the FDA-approved indicated uses in the creation of an anterior capsulotomy and laser phacofragmentation during cataract surgery. The

LenSx includes separate and distinct modes of operation, the "Capsule" and "Lens" Programs, that perform anterior capsulotomy and laser phacofragmentation in an infringing manner, and for which there is no substantial noninfringing use. Using the LenSx for the FDA-approved indications of anterior capsulotomy and laser phacofragmentation during cataract surgery is not a staple article or commodity of commerce, and does not have a substantial noninfringing use. Upon information and belief, customers have no practical ability to modify or use the LenSx for the indicated uses of anterior capsulotomy and laser phacofragmentation in a way to avoid infringement of the '001 patent.

201. Alcon has infringed and continues to infringe the '001 patent by supplying or causing to be supplied in or from the United States, without authority, all or a substantial portion of the components of the patented invention, including but not limited to the LenSx (in either assembled or unassembled form), parts and software for the LenSx, and consumables such as the LenSx SoftFit Patient Interface, where such components are uncombined in whole or in part, in such a manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, in violation of 35 U.S.C. § 271(f)(1). The components include but are not limited to the hardware and software components that are used to enable and perform the "Capsule" and "Lens" Programs that perform the FDA-approved anterior capsulotomy and laser phacofragmentation in an infringing manner. Alcon's inducing acts include instructions on assembly and use of the LenSx and consumables for use with the LenSx, marketing the LenSx, and providing installation, maintenance, service, and/or repair of the LenSx. Alcon has stated that the "LenSx® Laser requires use of proprietary sterile disposable Patient Interfaces." Alcon has further stated "[t]he consumables used in conjunction with ALCON® instrument products constitute a complete

surgical system." Additionally, upon information and belief, Alcon publishes and provides product documentation and educational materials that instruct and encourage its customers to use the LenSx for its FDA-approved indications and in an infringing manner, including providing the information relevant to each of the claim limitations that is referenced and/or quoted in the paragraphs above, with knowledge and/or with willful blindness that the induced acts constitute patent infringement.

202. Alcon has infringed and continues to infringe the '001 patent by supplying or causing to be supplied in or from the United States, without authority, at least one component of the patented invention, including but not limited to the LenSx (in either assembled or unassembled form), and parts and software for the LenSx, that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component(s) will be combined outside of the United States in a manner that infringe the patent if such combination occurred within the United States, in violation of 35 U.S.C. § 271(f)(2). The components include but are not limited to the hardware and software components that are used to enable and perform the "Capsule" and "Lens" Programs that perform the FDA-approved anterior capsulotomy and laser phacofragmentation in an infringing manner, including as set forth limitation-by-limitation in the paragraphs above, and for which there are no substantial noninfringing uses. Using the LenSx for the FDA-approved indicated uses of anterior capsulotomy and laser phacofragmentation during cataract surgery is not a staple article or commodity of commerce, and does not have a substantial noninfringing use. Upon information and belief, customers have no practical ability to modify or

use the LenSx or the components thereto for the indicated uses of anterior capsulotomy and laser phacofragmentation in a way to avoid infringement of the '001 patent.

203. Alcon is not licensed under the '001 patent.

204. The marking requirement of 35 U.S.C. § 287(a) has been satisfied through J&J Surgical Vision's marking of the Catalys® Precision Laser System.

205. J&J Surgical Vision has been damaged and will continue to be damaged by Alcon's infringement of the '001 patent.

206. J&J Surgical Vision has suffered and will continue to suffer irreparable harm unless and until Alcon's infringing activities are enjoined by this Court. J&J Surgical Vision does not have an adequate remedy at law.

207. Despite Alcon's knowledge of the '001 patent and of its infringing activities, Alcon has continued to manufacture, use, offer to sell, and/or sell the LenSx. Alcon's infringement of the '001 patent has been willful, making this an exceptional case and entitling J&J Surgical Vision to an award of increased damages and attorneys' fees.

COUNT VI
Infringement of the '415 Patent

208. J&J Surgical Vision incorporates by reference the allegations set forth in paragraphs 1 through 207 as though fully set forth herein.

209. Alcon has directly and indirectly infringed, and continues to infringe, literally or under the doctrine of equivalents, one or more claims of the '415 patent, by making, using, offering to sell, and/or selling the LenSx and consumables in the United States, without authority or license, in violation of 35 U.S.C. § 271.

210. For example, the LenSx meets each limitation of at least claim 1 of the '415 patent, which claims:

A method for incising ocular tissue during a cataract surgical procedure, the method comprising:

operating an imaging device to acquire image data of ocular tissue, the image data including lens interior image data for an interior portion of the lens of a patient's eye;

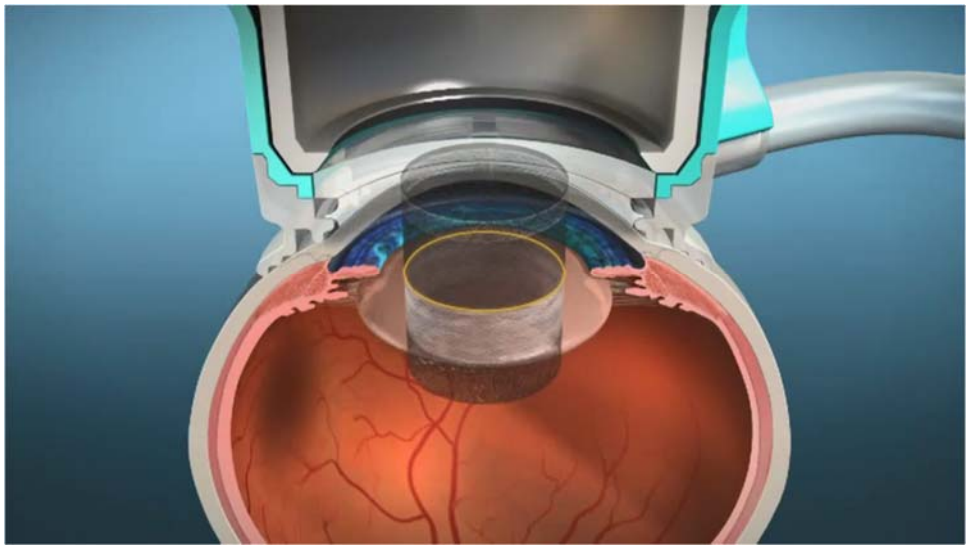
processing the image data via a control system so as to generate an anterior capsulotomy scanning pattern for scanning a focal zone of a laser beam for performing an anterior capsulotomy, the imaging device being operatively coupled to the control system;

generating the laser beam; and

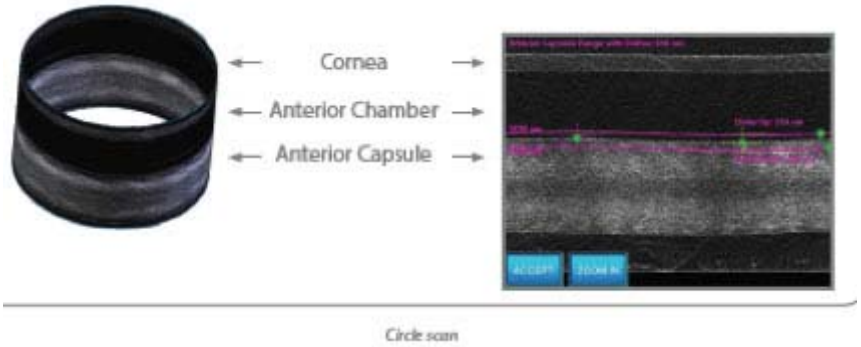
scanning the focal zone of the laser beam in the anterior capsulotomy scanning pattern so as to perform the anterior capsulotomy, wherein positioning of the focal zone is controlled by the control system based on the image data.

211. The LenSx practices a method for incising ocular tissue during a cataract surgical procedure. For example, Alcon has stated that "[t]he LenSx® Laser is indicated for use in patients undergoing cataract surgery … The LenSx® Laser creates incisions through tightly focused femtosecond laser pulses that cut tissue with micron-scale precision."

212. The LenSx operates an imaging device to acquire image data of ocular tissue, the image data including lens interior image data for an interior portion of the lens of a patient's eye. For example, Alcon has stated that "[an OCT] consists of a low power visible wavelength light source that is scanned throughout the transparent structures of the anterior chamber of the eye. Light scattered from ocular structures and surfaces within the eye is analyzed to produce cross sectional images of the eye's anterior segment. Various sectioned images may be produced, including … circle and line scans of the lens and capsule." Alcon has illustrated a circle scan as follows:



The circle scan provides image data for an interior portion of the lens. For example, Alcon has shown an image of a circle scan as follows:



213. The LenSx processes the image data via a control system so as to generate an anterior capsulotomy scanning pattern for scanning a focal zone of a laser beam for performing an anterior capsulotomy, the imaging device being operatively coupled to the control system. For example, Alcon has stated that the LenSx "includes an optical coherence tomography (OCT) based imaging device that assists in localizing specific target locations." Alcon has also stated that a

"[c]ircle scan OCT image of the lens and capsule is displayed [on] the top right area of the Surgical Display. The circle scan is performed along the Capsule Pattern diameter as defined on the video microscope image of the eye." Alcon has also stated that "[t]he Capsule Pattern is used to perform an anterior capsulotomy of the crystalline lens." Alcon has also stated that "[t]he surgical effect is produced by scanning thousands of individual pulses" and the location of those pulses "is controlled by moving the focus of the laser beam to the desired surgical target location. A computer-controlled scanning system directs the laser beam throughout a three-dimensional pattern to produce an incision."

214. The LenSx generates the laser beam. For example, Alcon has stated that "the laser engine uses a conventional amplified laser design in which pulses with sufficient bandwidth are generated by an oscillator, amplified to higher energies, and finally compressed in time to femtosecond pulse duration…. The beam of compressed pulses from the laser then enters the energy monitoring assembly."

215. The LenSx scans the focal zone of the laser beam in the anterior capsulotomy scanning pattern so as to perform the anterior capsulotomy, wherein positioning of the focal zone is controlled by the control system based on the image data. For example, Alcon has stated that "[a] femtosecond light pulse[] is focused into a sufficiently small spot in order to achieve photodisruption of the tissue inside the focus. A tiny volume of tissue, a few microns in diameter, is thereby photodisrupted at the laser focus. A computer-controlled scanning system directs the focused laser beam throughout a three-dimensional pattern to produce an incision. … The location of the tissue photodisruption is controlled by moving the focus of the laser beam to the desired surgical target location." Alcon has also stated that a "[c]ircle scan OCT image of the lens and capsule is displayed [on] the top right area of the Surgical Display. The circle scan is performed

along the Capsule Pattern diameter as defined on the video microscope image of the eye." Alcon has also stated that "[t]he Capsule Pattern is used to perform an anterior capsulotomy of the crystalline lens." Alcon has stated that "[a]nterior capsulotomy patterns are programmed to cut from at least 100 microns below to 100 microns above the anterior capsule." Alcon has described the anterior capsulotomy pattern as a "treatment pattern" that "begins as a scanned circle located below the depth of the anterior capsule. Once a scanned circle is completed, a new circle is scanned a few microns above the first circle. As each circle is completed, a cylindrical incision is created. The pattern is automatically completed when the anterior extent of the incision is reached."

216. Alcon's use of the LenSx in the United States has infringed and continues to infringe the '415 patent under 35 U.S.C. § 271(a).

217. Alcon's customers in the United States have directly infringed and continue to directly infringe the '415 patent by using the LenSx for its FDA-approved indications (including anterior capsulotomy).

218. Alcon has actively induced and continues to actively induce infringement of the '415 patent by encouraging its customers to use the LenSx, with specific intent, knowledge and/or willful blindness that the induced acts constitute patent infringement, in violation of 35 U.S.C. § 271(b). Upon information and belief, Alcon's inducing acts include marketing the LenSx, supporting the ongoing use of the LenSx by providing consumables such as the LenSx SoftFit Patient Interface for use with the LenSx, and providing installation, maintenance, service, and/or repair of the LenSx. Alcon has stated that the "LenSx® Laser requires use of proprietary sterile disposable Patient Interfaces." Alcon has further stated "[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system." Alcon's inducing acts also include providing instructions to use the LenSx for its FDA-approved indications (including

anterior capsulotomy) in an infringing manner, including providing the information relevant to each of the claim limitations that is referenced and/or quoted in the paragraphs above. Additionally, upon information and belief, Alcon has published and provided product documentation and educational materials that instruct and encourage its customers to use the LenSx for its FDA-approved indications in an infringing manner, with knowledge and/or with willful blindness that the induced acts constitute patent infringement. Moreover, upon information and belief, Alcon warns customers in the Operator's Manual for the LenSx that its "instructions must be observed."

219. Alcon has known of the '415 patent and of its infringement prior to this litigation, and it is further on notice through this lawsuit. Alcon's knowledge of the '415 patent, together with its knowledge about the design and operation of the LenSx, gave Alcon knowledge that its customers' use of the LenSx constitutes patent infringement, because the language of the '415 patent claims plainly reads upon the LenSx. Alcon's knowledge of infringement is also demonstrated by its receipt of correspondence and infringement charts specifically identifying its infringing acts, the allegations contained in the original complaint, its prior knowledge of the patent and the subject matter claimed, its statements touting the advantages of features that it knew to be patented, and the affirmative measures it took to address its risk of liability for patent infringement. Alcon's specific intent to induce infringement is demonstrated by its continued infringing acts despite this knowledge.

220. Alcon has contributed to and continues to contribute to infringement of the '415 patent by offering to sell and selling the LenSx that its customers use to infringe the patent, in violation of 35 U.S.C. § 271(c). Alcon does so knowing that the LenSx constitutes a material part of the invention, and that it is especially made and especially adapted for use in an infringement

of the patent. The LenSx is designed and configured so that the customer will use the system to perform FDA-approved anterior capsulotomy in a manner that infringes the patent, including as set forth limitation-by-limitation in the paragraphs above. The customer necessarily infringes the patent when it uses the LenSx for the FDA-approved indicated use in the creation of an anterior capsulotomy during cataract surgery. The LenSx includes a separate and distinct mode of operation, the "Capsule" Program, that performs anterior capsulotomy in an infringing manner, and for which there is no substantial noninfringing use. Using the LenSx for the FDA-approved indication of anterior capsulotomy during cataract surgery is not a staple article or commodity of commerce, and does not have a substantial noninfringing use. Upon information and belief, customers have no practical ability to modify or use the LenSx for the indicated use of anterior capsulotomy in a way to avoid infringement of the '415 patent.

221. Alcon is not licensed under the '415 patent.

222. J&J Surgical Vision has been damaged and will continue to be damaged by Alcon's infringement of the '415 patent.

223. J&J Surgical Vision has suffered and will continue to suffer irreparable harm unless and until Alcon's infringing activities are enjoined by this Court. J&J Surgical Vision does not have an adequate remedy at law.

224. Despite Alcon's knowledge of the '415 patent and of its infringing activities, Alcon has continued to manufacture, use, offer to sell, and/or sell the LenSx. Alcon's infringement of the '415 patent has been willful, making this an exceptional case and entitling J&J Surgical Vision to an award of increased damages and attorneys' fees.

COUNT VII
Infringement of the '448 Patent

225. J&J Surgical Vision incorporates by reference the allegations set forth in paragraphs 1 through 224 as though fully set forth herein.

226. Alcon has directly and indirectly infringed, and continues to infringe, literally or under the doctrine of equivalents, one or more claims of the '448 patent, by making, using, offering to sell, and/or selling the LenSx and consumables in the United States, and supplying or causing to be supplied the LenSx and consumables from the United States for use abroad, without authority or license, in violation of 35 U.S.C. § 271.

227. For example, the LenSx meets each limitation of claim 1 of the '448 patent, which claims:

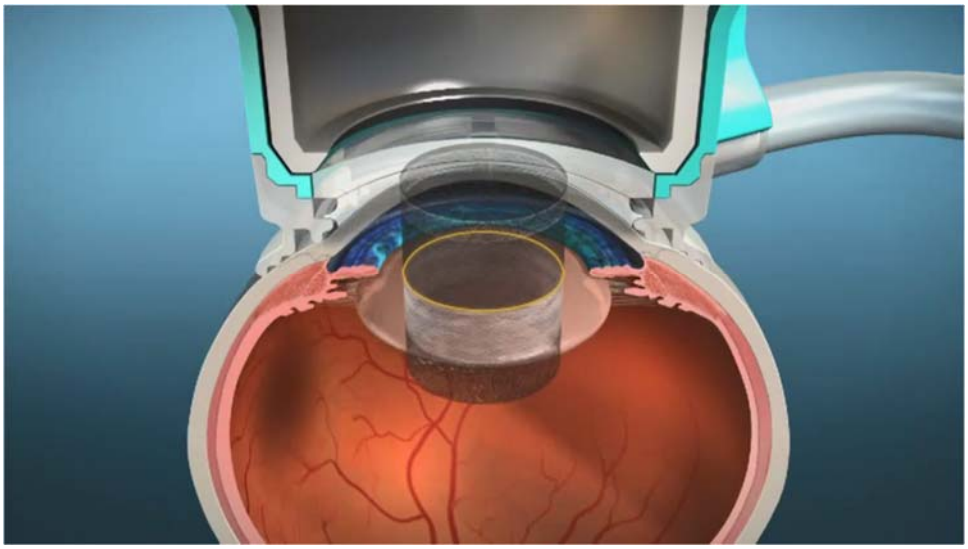
> A laser surgical system for making incisions in ocular tissue during a cataract surgical procedure, the system comprising:
>
> > a laser system comprising a scanning assembly, a laser operable to generate a laser beam configured to incise ocular issue, and an imaging device; and
> >
> > a control system operably coupled to the laser system and configured to:
> >
> > > operate the imaging device to generate image data for ocular tissue of a patient's eye, the image data including lens interior image data for an interior portion of the lens of the patient's eye;
> > >
> > > process the image data to determine an anterior capsulotomy scanning pattern for scanning a focal zone of the laser beam for performing an anterior capsulotomy; and
> > >
> > > operate the laser and the scanning assembly to scan the focal zone of the laser beam in the anterior capsulotomy scanning pattern to perform the anterior capsulotomy,
> > >
> > > > wherein positioning of the focal zone is guided by the control system based on the image data.

228. The LenSx is a laser surgical system for making incisions in ocular tissue during a cataract surgical procedure. For example, Alcon has stated that "[t]he LenSx® Laser is indicated

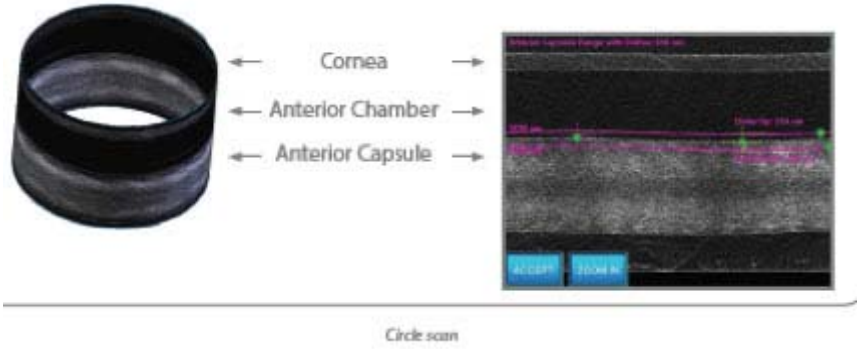
for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, phacofragmentation, and the creation of single plane and multi-plane arc cuts/incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure. … The LenSx® Laser creates incisions through tightly focused femtosecond laser pulses that cut tissue with micron-scale precision."

229. The LenSx has a laser system comprising a scanning assembly, a laser operable to generate a laser beam configured to incise ocular tissue, and an imaging device. For example, Alcon has stated that the LenSx device console "houses the laser source, power supplies, control electronics, cooling system, beam delivery device, optical coherence tomography (OCT) device, video microscope and computers." Alcon has also stated that the LenSx has "an ophthalmic surgical laser which uses focused femtosecond laser pulses to create incisions and to separate tissue within the lens capsule, crystalline lens, and the cornea." Alcon has also stated that "[a] computer-controlled scanning system directs the laser beam throughout a three-dimensional pattern to produce an incision."

230. The LenSx has a control system operably coupled to the laser system and configured to operate the imaging device to generate image data for ocular tissue of a patient's eye, the image data including lens interior image data for an interior portion of the lens of the patient's eye. For example, Alcon has stated that "[a] computer monitors and controls the beam energy, repetition rate, safety shutters, footswitch, laser diagnostics, the position of the scanners and the position of the scanning objective lens." Upon information and belief, the LenSx uses its OCT imaging to generate what Alcon refers to as a circle scan. For example, Alcon has illustrated a circle scan as follows:



The circle scan provides image data for an interior portion of the patient's eye. For example, Alcon has shown an image of a circle scan as follows:



231. The LenSx has a control system operably coupled to the laser system and configured to process the image data to determine an anterior capsulotomy scanning pattern for scanning a focal zone of the laser beam for performing an anterior capsulotomy. For example, Alcon has stated that the LenSx "includes an optical coherence tomography (OCT) based imaging device that assists in localizing specific target locations." Alcon has also stated that a "[c]ircle scan OCT image of the lens and capsule is displayed [on] the top right area of the Surgical Display. The circle scan is performed along the Capsule Pattern diameter as defined on the video microscope

image of the eye." Alcon has also stated that "[t]he Capsule Pattern is used to perform an anterior capsulotomy of the crystalline lens." Alcon has also stated that "[t]he surgical effect is produced by scanning thousands of individual pulses" and the location of those pulses "is controlled by moving the focus of the laser beam to the desired surgical target location. A computer-controlled scanning system directs the laser beam throughout a three-dimensional pattern to produce an incision."

232. The LenSx has a control system operably coupled to the laser system and configured to operate the laser and the scanning assembly to scan the focal zone of the laser beam in the anterior capsulotomy scanning pattern to perform the anterior capsulotomy, wherein positioning of the focal zone is guided by the control system based on the image data. For example, Alcon has stated that in the LenSx, "[a] computer monitors and controls the beam energy, repetition rate, safety shutters, footswitch, laser diagnostics, the position of the scanners and the position of the scanning objective lens." Alcon has also stated that a "[c]ircle scan OCT image of the lens and capsule is displayed [on] the top right area of the Surgical Display. The circle scan is performed along the Capsule Pattern diameter as defined on the video microscope image of the eye." Alcon has also stated that "[t]he Capsule Pattern is used to perform an anterior capsulotomy of the crystalline lens." Alcon has also stated that "[t]he surgical effect is produced by scanning thousands of individual pulses" and the location of those pulses "is controlled by moving the focus of the laser beam to the desired surgical target location. A computer-controlled scanning system directs the laser beam throughout a three-dimensional pattern to produce an incision…. The location of the tissue photodisruption is controlled by moving the focus of the laser beam to the desired surgical target location."

233. Alcon's manufacture, use, offer to sell, and sale of the LenSx in the United States has infringed and continues to infringe the '448 patent under 35 U.S.C. § 271(a).

234. Alcon's customers in the United States have directly infringed and continue to directly infringe the '448 patent by using the LenSx for its FDA-approved indications (including anterior capsulotomy).

235. Alcon has actively induced and continues to actively induce infringement of the '448 patent by encouraging its customers to use the LenSx, with specific intent, knowledge and/or willful blindness that the induced acts constitute patent infringement, in violation of 35 U.S.C. § 271(b). Upon information and belief, Alcon's inducing acts include marketing the LenSx, supporting the ongoing use of the LenSx by providing consumables such as the LenSx SoftFit Patient Interface for use with the LenSx, and providing installation, maintenance, service, and/or repair of the LenSx. Alcon has stated that the "LenSx® Laser requires use of proprietary sterile disposable Patient Interfaces." Alcon has further stated "[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system." Alcon's inducing acts also include providing instructions to use the LenSx for its FDA-approved indications (including anterior capsulotomy) in an infringing manner, including providing the information relevant to each of the claim limitations that is referenced and/or quoted in the paragraphs above. Additionally, upon information and belief, Alcon has published and provided product documentation and educational materials that instruct and encourage its customers to use the LenSx for its FDA-approved indications in an infringing manner, with knowledge and/or with willful blindness that the induced acts constitute patent infringement. Moreover, upon information and belief, Alcon warns customers in the Operator's Manual for the LenSx that its "instructions must be observed."

236. Alcon has known of the ’448 patent and of its infringement prior to this litigation, and it is further on notice through this lawsuit. Alcon’s knowledge of the ’448 patent, together with its knowledge about the design and operation of the LenSx, gave Alcon knowledge that its customers’ use of the LenSx constitutes patent infringement, because the language of the ’448 patent claims plainly reads upon the LenSx. Alcon’s knowledge of infringement is also demonstrated by its receipt of correspondence and infringement charts specifically identifying its infringing acts, the allegations contained in the original complaint, its prior knowledge of the patent and the subject matter claimed, its statements touting the advantages of features that it knew to be patented, and the affirmative measures it took to address its risk of liability for patent infringement. Alcon’s specific intent to induce infringement is demonstrated by its continued infringing acts despite this knowledge.

237. Alcon has contributed to and continues to contribute to infringement of the ’448 patent by offering to sell and selling the LenSx that its customers use to infringe the patent, in violation of 35 U.S.C. § 271(c). Alcon does so knowing that the LenSx constitutes a material part of the invention, and that it is especially made and especially adapted for use in an infringement of the patent. The LenSx is designed and configured so that the customer will use the system to perform FDA-approved anterior capsulotomy in a manner that infringes the patent, including as set forth limitation-by-limitation in the paragraphs above. The customer necessarily infringes the patent when it uses the LenSx for the FDA-approved indicated use in the creation of an anterior capsulotomy during cataract surgery. The LenSx includes a separate and distinct mode of operation, the “Capsule” Program, that performs anterior capsulotomy in an infringing manner, and for which there is no substantial noninfringing use. Using the LenSx for the FDA-approved indications of anterior capsulotomy during cataract surgery is not a staple article or commodity of

commerce, and does not have a substantial noninfringing use. Upon information and belief, customers have no practical ability to modify or use the LenSx for the indicated use of anterior capsulotomy in a way to avoid infringement of the '448 patent.

238. Alcon has infringed and continues to infringe the '448 patent by supplying or causing to be supplied in or from the United States, without authority, all or a substantial portion of the components of the patented invention, including but not limited to the LenSx (in either assembled or unassembled form), parts and software for the LenSx, and consumables such as the LenSx SoftFit Patient Interface, where such components are uncombined in whole or in part, in such a manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, in violation of 35 U.S.C. § 271(f)(1). The components include but are not limited to the hardware and software components that are used to enable and perform the "Capsule" Program that performs the FDA-approved anterior capsulotomy in an infringing manner. Alcon's inducing acts include instructions on assembly and use of the LenSx and consumables for use with the LenSx, marketing the LenSx, and providing installation, maintenance, service, and/or repair of the LenSx. Alcon has stated that the "LenSx® Laser requires use of proprietary sterile disposable Patient Interfaces." Alcon has further stated "[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system." Additionally, upon information and belief, Alcon publishes and provides product documentation and educational materials that instruct and encourage its customers to use the LenSx for its FDA-approved indications for use and in an infringing manner, including providing the information relevant to each of the claim limitations that is referenced and/or quoted in the paragraphs above, with knowledge and/or with willful blindness that the induced acts constitute patent infringement.

239. Alcon has infringed and continues to infringe the '448 patent by supplying or causing to be supplied in or from the United States, without authority, at least one component of the patented invention, including but not limited to the LenSx (in either assembled or unassembled form), and parts and software for the LenSx, that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component(s) will be combined outside of the United States in a manner that infringe the patent if such combination occurred within the United States, in violation of 35 U.S.C. § 271(f)(2). The components include but are not limited to the hardware and software components that are used to enable and perform the "Capsule" Program that performs the FDA-approved anterior capsulotomy in an infringing manner, including as set forth limitation-by-limitation in the paragraphs above, and for which there are no substantial noninfringing uses. Using the LenSx for the FDA-approved indicated use of anterior capsulotomy during cataract surgery is not a staple article or commodity of commerce, and does not have a substantial noninfringing use. Upon information and belief, customers have no practical ability to modify or use the LenSx or the components thereto for the indicated use of anterior capsulotomy in a way to avoid infringement of the '448 patent.

240. Alcon is not licensed under the '448 patent.

241. The marking requirement of 35 U.S.C. § 287(a) has been satisfied through J&J Surgical Vision's marking of the Catalys® Precision Laser System.

242. J&J Surgical Vision has been damaged and will continue to be damaged by Alcon's infringement of the '448 patent.

243. J&J Surgical Vision has suffered and will continue to suffer irreparable harm unless and until Alcon's infringing activities are enjoined by this Court. J&J Surgical Vision does not have an adequate remedy at law.

244. Despite Alcon's knowledge of the '448 patent and of its infringing activities, Alcon has continued to manufacture, use, offer to sell, and/or sell the LenSx. Alcon's infringement of the '448 patent has been willful, making this an exceptional case and entitling J&J Surgical Vision to an award of increased damages and attorneys' fees.

COUNT VIII
Infringement of the '732 Patent

245. J&J Surgical Vision incorporates by reference the allegations set forth in paragraphs 1 through 244 as though fully set forth herein.

246. Alcon has directly and indirectly infringed, and continues to infringe, literally or under the doctrine of equivalents, one or more claims of the '732 patent, by making, using, offering to sell, and/or selling the LenSx and consumables in the United States, and supplying or causing to be supplied the LenSx and consumables from the United States for use abroad, without authority or license, in violation of 35 U.S.C. § 271.

247. For example, the LenSx meets each limitation of claim 1 of the '732 patent, which claims:

> A laser surgical system for making incisions in ocular tissue during a cataract surgical procedure, the system comprising:
>
> a laser operable to generate a laser beam for incising ocular tissue;
>
> a scanning assembly operable to direct a focal zone of the laser beam to locations within a patient's eye;
>
> an optical coherence tomography (OCT) imaging device; and
>
> a control system operably coupled to the laser, the scanning assembly, and the OCT imaging device; the control system being configured to:

> operate the OCT imaging device to generate image data for ocular tissue of the patient, the image data including lens interior image data for an interior portion of the lens of the patient's eye;
>
> process the image data to determine an anterior capsulotomy scanning pattern for scanning the focal zone of the laser beam for performing an anterior capsulotomy; and
>
> operate the laser and the scanning assembly to scan the focal zone of the laser beam in the anterior capsulotomy scanning pattern so as to perform the anterior capsulotomy, wherein positioning of the focal zone is guided by the control system based on the image data.

248. The LenSx is a laser surgical system for making incisions in ocular tissue during a cataract surgical procedure. For example, Alcon has stated that "[t]he LenSx® Laser is indicated for use in patients undergoing cataract surgery…. The LenSx® Laser creates incisions through tightly focused femtosecond laser pulses that cut tissue with micron-scale precision."

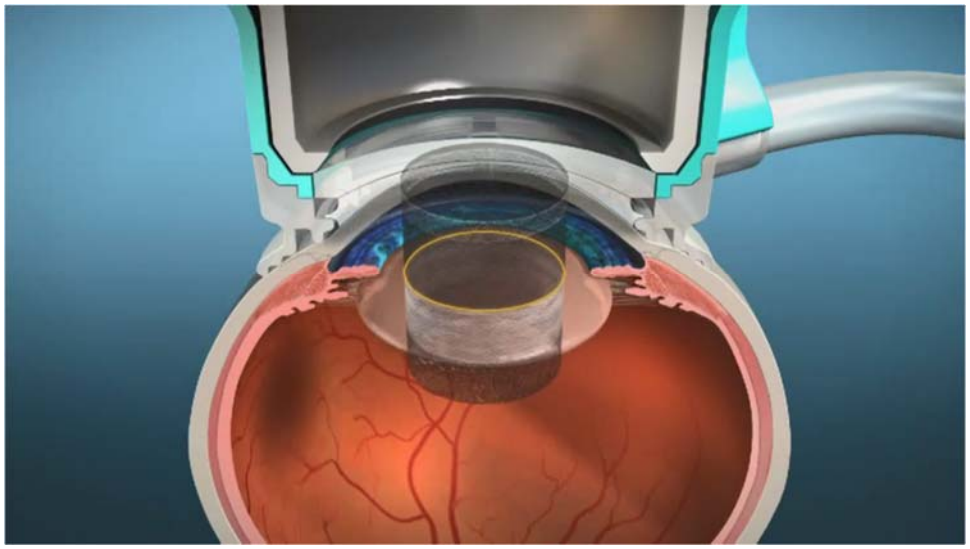
249. The LenSx has a laser operable to generate a laser beam for incising ocular tissue. For example, Alcon has stated that the LenSx device console "houses the laser source, power supplies, control electronics, cooling system, beam delivery device, optical coherence tomography (OCT) device, video microscope and computers." Alcon has also stated that the LenSx "uses focused femtosecond laser pulses to create incisions and separates tissue in the lens capsule, crystalline lens and cornea."

250. The LenSx has a scanning assembly operable to direct a focal zone of the laser beam to locations within a patient's eye. For example, Alcon has stated that the LenSx has "an ophthalmic surgical laser which uses focused femtosecond laser pulses to create incisions and to separate tissue within the lens capsule, crystalline lens, and the cornea. A femtosecond light pulse[] is focused into a sufficiently small spot in order to achieve photodisruption of the tissue inside the focus. A tiny volume of tissue, a few microns in diameter, is thereby photodisrupted at the laser

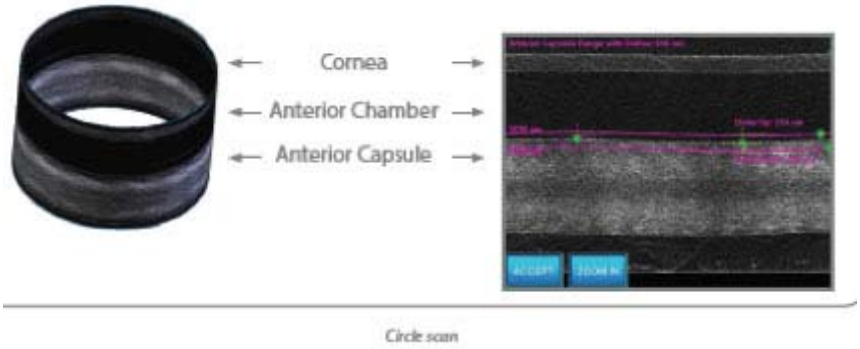
focus. A computer-controlled scanning system directs the focused laser beam throughout a three-dimensional pattern to produce an incision."

251. The LenSx has an optical coherence tomography (OCT) imaging device. For example, Alcon has stated that the LenSx device console "houses the laser source, power supplies, control electronics, cooling system, beam delivery device, optical coherence tomography (OCT) device, video microscope and computers."

252. The LenSx has a control system operably coupled to the laser, the scanning assembly, and the OCT imaging device; the control system being configured to operate the OCT imaging device to generate image data for ocular tissue of the patient, the image data including lens interior image data for an interior portion of the lens of the patient's eye. For example, Alcon has stated that "[a] computer monitors and controls the beam energy, repetition rate, safety shutters, footswitch, laser diagnostics, the position of the scanners and the position of the scanning objective lens." Upon information and belief, the LenSx uses its OCT imaging device to generate what Alcon refers to as a circle scan. For example, Alcon has illustrated a circle scan as follows:



The circle scan provides image data for an interior portion of the lens of the patient's eye. For example, Alcon has shown an image of a circle scan as follows:



253. The LenSx has a control system operably coupled to the laser, the scanning assembly, and the OCT imaging device; the control system being configured to process the image data to determine an anterior capsulotomy scanning pattern for scanning the focal zone of the laser beam for performing an anterior capsulotomy. For example, Alcon has stated that the LenSx "includes an optical coherence tomography (OCT) based imaging device that assists in localizing specific target locations." Alcon has also stated that a "[c]ircle scan OCT image of the lens and capsule is displayed [on] the top right area of the Surgical Display. The circle scan is performed along the Capsule Pattern diameter as defined on the video microscope image of the eye." Alcon has also stated that "[t]he Capsule Pattern is used to perform an anterior capsulotomy of the crystalline lens." Alcon has also stated that in the LenSx, "a computer-controlled scanning system directs the laser beam throughout a three-dimensional pattern to produce an incision…. The location of the tissue photodisruption is controlled by moving the focus of the laser beam to the desired surgical target location." Upon information and belief, the LenSx is indicated for use in the creation of an anterior capsulotomy. Alcon has stated that "[a]nterior capsulotomy patterns are programmed to cut from at least 100 microns below and 100 microns above the anterior capsule." Alcon has described the anterior capsulotomy pattern as a "treatment pattern" that "begins as a scanned circle located below the depth of the anterior capsule. Once a scanned circle is completed,

a new circle is scanned a few microns above the first circle. As each circle is completed, a cylindrical incision is created. The pattern is automatically completed when the anterior extent of the incision is reached."

254. The LenSx has a control system operably coupled to the laser, the scanning assembly, and the OCT imaging device; the control system being configured to operate the laser and the scanning assembly to scan the focal zone of the laser beam in the anterior capsulotomy scanning pattern so as to perform the anterior capsulotomy, wherein positioning of the focal zone is guided by the control system based on the image data. For example, Alcon has stated that a "[c]ircle scan OCT image of the lens and capsule is displayed [on] the top right area of the Surgical Display. The circle scan is performed along the Capsule Pattern diameter as defined on the video microscope image of the eye." Alcon has also stated that "[t]he Capsule Pattern is used to perform an anterior capsulotomy of the crystalline lens." Alcon has also stated that "[t]he surgical effect is produced by scanning thousands of individual pulses" and the location of those pulses "is controlled by moving the focus of the laser beam to the desired surgical target location. A computer-controlled scanning system directs the laser beam throughout a three-dimensional pattern to produce an incision."

255. Alcon's manufacture, use, offer to sell, and sale of the LenSx in the United States has infringed and continues to infringe the '732 patent under 35 U.S.C. § 271(a).

256. Alcon's customers in the United States have directly infringed and continue to directly infringe the '732 patent by using the LenSx for its FDA-approved indications (including anterior capsulotomy).

257. Alcon has actively induced and continues to actively induce infringement of the '732 patent by encouraging its customers to use the LenSx, with specific intent, knowledge and/or

willful blindness that the induced acts constitute patent infringement, in violation of 35 U.S.C. § 271(b). Upon information and belief, Alcon's inducing acts include marketing the LenSx, supporting the ongoing use of the LenSx by providing consumables such as the LenSx SoftFit Patient Interface for use with the LenSx, and providing installation, maintenance, service, and/or repair of the LenSx. Alcon has stated that the "LenSx® Laser requires use of proprietary sterile disposable Patient Interfaces." Alcon has further stated "[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system." Alcon's inducing acts also include providing instructions to use the LenSx for its FDA-approved indications (including anterior capsulotomy) in an infringing manner, including providing the information relevant to each of the claim limitations that is referenced and/or quoted in the paragraphs above. Additionally, upon information and belief, Alcon has published and provided product documentation and educational materials that instruct and encourage its customers to use the LenSx for its FDA-approved indications in an infringing manner, with knowledge and/or with willful blindness that the induced acts constitute patent infringement. Moreover, upon information and belief, Alcon warns customers in the Operator's Manual for the LenSx that its "instructions must be observed."

258. Alcon has known of the '732 patent and of its infringement prior to this litigation, and it is further on notice through this lawsuit. Alcon's knowledge of the '732 patent, together with its knowledge about the design and operation of the LenSx, gave Alcon knowledge that its customers' use of the LenSx constitutes patent infringement, because the language of the '732 patent claims plainly reads upon the LenSx. Alcon's knowledge of infringement is also demonstrated by its receipt of correspondence and infringement charts specifically identifying its infringing acts, the allegations contained in the original complaint, its prior knowledge of the

patent and the subject matter claimed, its statements touting the advantages of features that it knew to be patented, and the affirmative measures it took to address its risk of liability for patent infringement. Alcon's specific intent to induce infringement is demonstrated by its continued infringing acts despite this knowledge.

259. Alcon has contributed to and continues to contribute to infringement of the '732 patent by offering to sell and selling the LenSx that its customers use to infringe the patent, in violation of 35 U.S.C. § 271(c). Alcon does so knowing that the LenSx constitutes a material part of the invention, and that it is especially made and especially adapted for use in infringing the patent. The LenSx is designed and configured so that the customer will use the system to perform FDA-approved anterior capsulotomy in a manner that infringes the patent, including as set forth limitation-by-limitation in the paragraphs above. The customer necessarily infringes the patent when it uses the LenSx for the FDA-approved indicated use in the creation of an anterior capsulotomy during cataract surgery. The LenSx includes a separate and distinct mode of operation, the "Capsule" Program, that performs anterior capsulotomy in an infringing manner, and for which there is no substantial noninfringing use. Using the LenSx for the FDA-approved indications of anterior capsulotomy during cataract surgery is not a staple article or commodity of commerce, and does not have a substantial noninfringing use. Upon information and belief, customers have no practical ability to modify or use the LenSx for the indicated use of anterior capsulotomy in a way to avoid infringement of the '732 patent.

260. Alcon has infringed and continues to infringe the '732 patent by supplying or causing to be supplied in or from the United States, without authority, all or a substantial portion of the components of the patented invention, including but not limited to the LenSx (in either assembled or unassembled form), parts and software for the LenSx, and consumables such as the

LenSx SoftFit Patient Interface, where such components are uncombined in whole or in part, in such a manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, in violation of 35 U.S.C. § 271(f)(1). The components include but are not limited to the hardware and software components that are used to enable and perform the "Capsule" Program that performs the FDA-approved anterior capsulotomy in an infringing manner. Alcon's inducing acts include instructions on assembly and use of the LenSx and consumables for use with the LenSx, marketing the LenSx, and providing installation, maintenance, service, and/or repair of the LenSx. Alcon has stated that the "LenSx® Laser requires use of proprietary sterile disposable Patient Interfaces." Alcon has further stated "[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system." Additionally, upon information and belief, Alcon publishes and provides product documentation and educational materials that instruct and encourage its customers to use the LenSx for its FDA-approved indications for use and in an infringing manner, including providing the information relevant to each of the claim limitations that is referenced and/or quoted in the paragraphs above, with knowledge and/or with willful blindness that the induced acts constitute patent infringement.

261. Alcon has infringed and continues to infringe the '732 patent by supplying or causing to be supplied in or from the United States, without authority, at least one component of the patented invention, including but not limited to the LenSx (in either assembled or unassembled form), and parts and software for the LenSx, that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component(s) will be combined outside

of the United States in a manner that infringe the patent if such combination occurred within the United States, in violation of 35 U.S.C. § 271(f)(2). The components include but are not limited to the hardware and software components that are used to enable and perform the "Capsule" Program that performs the FDA-approved anterior capsulotomy in an infringing manner, including as set forth limitation-by-limitation in the paragraphs above, and for which there are no substantial noninfringing uses. Using the LenSx for the FDA-approved indicated use of anterior capsulotomy during cataract surgery is not a staple article or commodity of commerce, and does not have a substantial noninfringing use. Upon information and belief, customers have no practical ability to modify or use the LenSx or the components thereto for the indicated use of anterior capsulotomy in a way to avoid infringement of the '732 patent.

262. Alcon is not licensed under the '732 patent.

263. The marking requirement of 35 U.S.C. § 287(a) has been satisfied through J&J Surgical Vision's marking of the Catalys® Precision Laser System.

264. J&J Surgical Vision has been damaged and will continue to be damaged by Alcon's infringement of the '732 patent.

265. J&J Surgical Vision has suffered and will continue to suffer irreparable harm unless and until Alcon's infringing activities are enjoined by this Court. J&J Surgical Vision does not have an adequate remedy at law.

266. Despite Alcon's knowledge of the '732 patent and of its infringing activities, Alcon has continued to manufacture, use, offer to sell, and/or sell the LenSx. Alcon's infringement of the '732 patent has been willful, making this an exceptional case and entitling J&J Surgical Vision to an award of increased damages and attorneys' fees.

COUNT IX
Infringement of the '725 Patent

267. J&J Surgical Vision incorporates by reference the allegations set forth in paragraphs 1 through 266 as though fully set forth herein.

268. Alcon has directly and indirectly infringed, and continues to infringe, literally or under the doctrine of equivalents, one or more claims of the '725 patent, by making, using, offering to sell, and/or selling the LenSx and consumables in the United States, and supplying or causing to be supplied the LenSx and consumables from the United States for use abroad, without authority or license, in violation of 35 U.S.C. § 271.

269. For example, the LenSx meets each limitation of claim 1 of the '725 patent, which claims:

> A laser surgical system for making incisions in ocular tissues during a cataract surgical procedure, the system comprising:
>
> > a laser system comprising a scanning assembly, a laser operable to generate a laser beam configured to incise ocular tissue;
> >
> > an imaging device configured to acquire point by point image data from locations distributed throughout a volume of a crystalline lens of the patient and construct one or more images of the patient's eye tissues from the image data, wherein the one or more images comprise an image of at least a portion of the crystalline lens; and
> >
> > a control system operably coupled to the laser system and configured to:
> >
> > > operate the imaging device to generate image data for patient's crystalline lens;
> > >
> > > process the image data to identify a location for each of one or more targets in the lens of the patient;
> > >
> > > process the image data to determine a treatment scanning pattern for scanning a focal zone of the laser beam for performing one or more incisions in the lens capsule; and
> > >
> > > operate the laser and the scanning assembly to scan the focal zone of the laser beam in the treatment scanning pattern at each location of the one or more targets, wherein positioning of the focal zone is

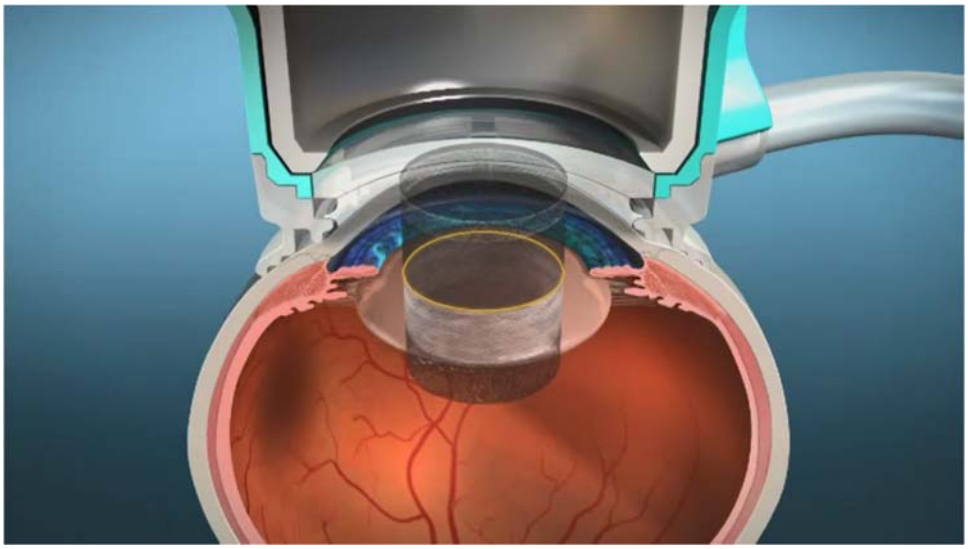
> guided by the control system based on the location of the one or more targets so as to perform the one or more incision in the lens capsule.

270. The LenSx is a laser surgical system for making incisions in ocular tissues during a cataract surgical procedure. For example, Alcon has stated that "[t]he LenSx® Laser is indicated for use in patients undergoing cataract surgery … The LenSx® Laser creates incisions through tightly focused femtosecond laser pulses that cut tissue with micron-scale precision."

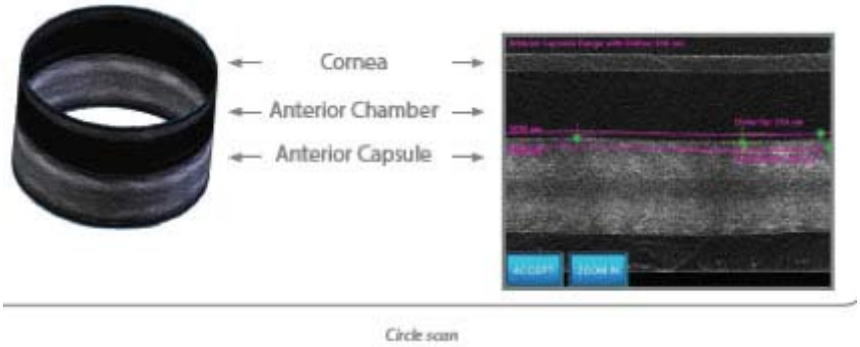
271. The LenSx has a laser system comprising a scanning assembly, a laser operable to generate a laser beam configured to incise ocular tissue. For example, Alcon has stated that the LenSx has "an ophthalmic surgical laser which uses focused femtosecond laser pulses to create incisions and to separate tissue within the lens capsule, crystalline lens, and the cornea. A femtosecond light pulse[] is focused into a sufficiently small spot in order to achieve photodisruption of the tissue inside the focus. A tiny volume of tissue, a few microns in diameter, is thereby photodisrupted at the laser focus. A computer-controlled scanning system directs the focused laser beam throughout a three-dimensional pattern to produce an incision."

272. The LenSx has an imaging device configured to acquire point by point image data from locations distributed throughout a volume of a crystalline lens of the patient and construct one or more images of the patient's eye tissues from the image data, wherein the one or more images comprise an image of at least a portion of the crystalline lens. For example, Alcon has stated that "[t]he OCT consists of a low power visible wavelength light source that is scanned throughout the transparent structures of the anterior chamber of the eye. Light scattered from ocular structures and surfaces within the eye is analyzed to produce cross sectional images of the eye's anterior segment. Various sectioned images may be produced, including a wide field line scan of the anterior chamber, magnified cross sections of the cornea at the points of planned incisions, and circle and line scans of the lens and capsule." Upon information and belief, the

LenSx uses its OCT imaging device to generate what Alcon refers to as a circle scan. For example, Alcon has illustrated a circle scan as follows:

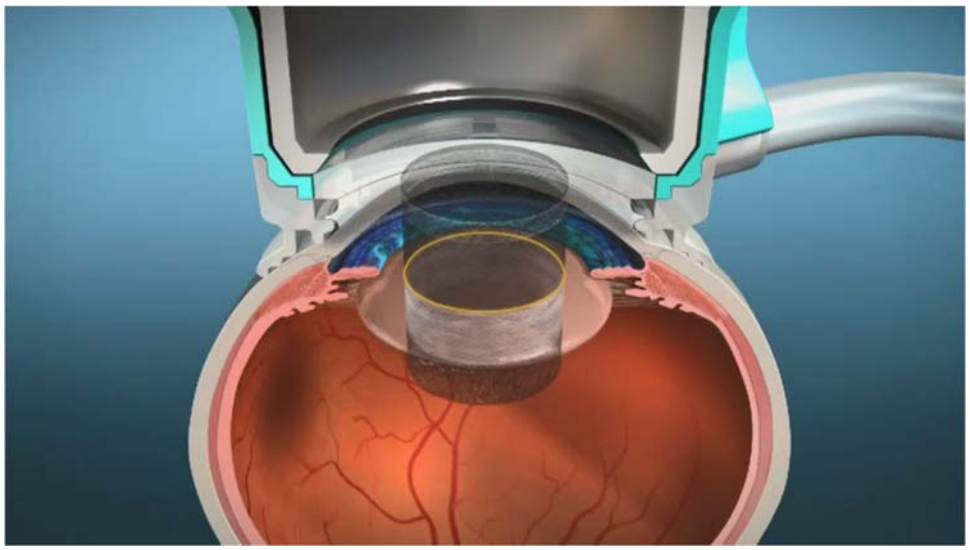


The circle scan provides an image of at least a portion of the crystalline lens. For example, Alcon has shown an image of a circle scan as follows:

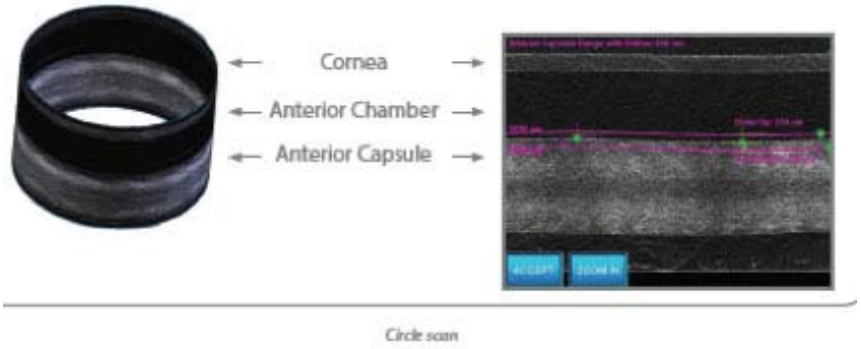


273. The LenSx has a control system operably coupled to the laser system and configured to operate the imaging device to generate image data for patient's crystalline lens. For example, Alcon has stated that "[a] computer monitors and controls the beam energy, repetition rate, safety shutters, footswitch, laser diagnostics, the position of the scanners and the position of the scanning objective lens." Upon information and belief, the LenSx uses its OCT imaging device

to generate what Alcon refers to as a circle scan. For example, Alcon has illustrated a circle scan as follows:



The circle scan provides an image of the patient's crystalline lens. For example, Alcon has shown an image of a circle scan as follows:



274. The LenSx has a control system operably coupled to the laser system and configured to process the image data to identify a location for each of one or more targets in the lens of the patient. For example, Alcon has stated that "[a] computer monitors and controls the beam energy, repetition rate, safety shutters, footswitch, laser diagnostics, the position of the scanners and the position of the scanning objective lens." Alcon has also stated that the LenSx "includes an optical coherence tomography (OCT) based imaging device that assists in localizing

specific target locations." Alcon has stated that in the LenSx, "a computer-controlled scanning system directs the laser beam throughout a three-dimensional pattern to produce an incision…. The location of the tissue photodisruption is controlled by moving the focus of the laser beam to the desired surgical target location."

275. The LenSx has a control system operably coupled to the laser system and configured to process the image data to determine a treatment scanning pattern for scanning a focal zone of the laser beam for performing one or more incisions in the lens capsule. For example, Alcon has stated that the LenSx "includes an optical coherence tomography (OCT) based imaging device that assists in localizing specific target locations." Alcon has also stated that a "[c]ircle scan OCT image of the lens and capsule is displayed [on] the top right area of the Surgical Display. The circle scan is performed along the Capsule Pattern diameter as defined on the video microscope image of the eye." Alcon has also stated that "[t]he Capsule Pattern is used to perform an anterior capsulotomy of the crystalline lens." Upon information and belief, an anterior capsulotomy requires performing one or more incisions in the lens capsule. Alcon has also stated that "[t]he surgical effect is produced by scanning thousands of individual pulses" and the location of those pulses "is controlled by moving the focus of the laser beam to the desired surgical target location. A computer-controlled scanning system directs the laser beam throughout a three-dimensional pattern to produce an incision."

276. The LenSx has a control system operably coupled to the laser system and configured to operate the laser and the scanning assembly to scan the focal zone of the laser beam in the treatment scanning pattern at each location of the one or more targets, wherein positioning of the focal zone is guided by the control system based on the location of the one or more targets so as to perform the one or more incision in the lens capsule. For example, Alcon has stated that

in the LenSx, "[a] computer monitors and controls the beam energy, repetition rate, safety shutters, footswitch, laser diagnostics, the position of the scanners and the position of the scanning objective lens." Alcon has stated that in the LenSx, "a computer-controlled scanning system directs the laser beam throughout a three-dimensional pattern to produce an incision…. The location of the tissue photodisruption is controlled by moving the focus of the laser beam to the desired surgical target location." Alcon has also stated that the LenSx "includes an optical coherence tomography (OCT) based imaging device that assists in localizing specific target locations." Upon information and belief, the LenSx is indicated for use in the creation of an anterior capsulotomy and laser phacofragmentation during cataract surgery. Upon information and belief an anterior capsulotomy requires performing one or more incisions in the lens capsule. For example, Alcon has described the anterior capsulotomy pattern as a "treatment pattern" that "begins as a scanned circle located below the depth of the anterior capsule. Once a scanned circle is completed, a new circle is scanned a few microns above the first circle. As each circle is completed, a cylindrical incision is created. The pattern is automatically completed when the anterior extent of the incision is reached."

277. Alcon's manufacture, use, offer to sell, and sale of the LenSx in the United States has infringed and continues to infringe the '725 patent under 35 U.S.C. § 271(a).

278. Alcon's customers in the United States have directly infringed and continue to directly infringe the '725 patent by using the LenSx for its FDA-approved indications (including anterior capsulotomy).

279. Alcon has actively induced and continues to actively induce infringement of the '725 patent by encouraging its customers to use the LenSx, with specific intent, knowledge and/or willful blindness that the induced acts constitute patent infringement, in violation of 35 U.S.C. § 271(b). Upon information and belief, Alcon's inducing acts include marketing the LenSx,

supporting the ongoing use of the LenSx by providing consumables such as the LenSx SoftFit Patient Interface for use with the LenSx, and providing installation, maintenance, service, and/or repair of the LenSx. Alcon has stated that the "LenSx® Laser requires use of proprietary sterile disposable Patient Interfaces." Alcon has further stated "[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system." Alcon's inducing acts also include providing instructions to use the LenSx for its FDA-approved indications (including anterior capsulotomy) in an infringing manner, including providing the information relevant to each of the claim limitations that is referenced and/or quoted in the paragraphs above. Additionally, upon information and belief, Alcon has published and provided product documentation and educational materials that instruct and encourage its customers to use the LenSx for its FDA-approved in an infringing manner, with knowledge and/or with willful blindness that the induced acts constitute patent infringement. Moreover, upon information and belief, Alcon warns customers in the Operator's Manual for the LenSx that its "instructions must be observed."

280. Alcon has known of the '725 patent and of its infringement prior to this litigation, and it is further on notice through this lawsuit. Alcon's knowledge of the '725 patent, together with its knowledge about the design and operation of the LenSx, gave Alcon knowledge that its customers' use of the LenSx constitutes patent infringement, because the language of the '725 patent claims plainly reads upon the LenSx. Alcon's knowledge of infringement is also demonstrated by its receipt of correspondence and infringement charts specifically identifying its infringing acts, the allegations contained in the original complaint, its prior knowledge of the patent and the subject matter claimed, its statements touting the advantages of features that it knew to be patented, and the affirmative measures it took to address its risk of liability for patent

infringement. Alcon's specific intent to induce infringement is demonstrated by its continued infringing acts despite this knowledge.

281. Alcon has contributed to and continues to contribute to infringement of the '725 patent by offering to sell and selling the LenSx that its customers use to infringe the patent, in violation of 35 U.S.C. § 271(c). Alcon does so knowing that the LenSx constitutes a material part of the invention, and that it is especially made and especially adapted for use in an infringement of the patent. The LenSx is designed and configured so that the customer will use the system to perform FDA-approved anterior capsulotomy in a manner that infringes the patent, including as set forth limitation-by-limitation in the paragraphs above. The customer necessarily infringes the patent when it uses the LenSx for the FDA-approved indicated use in the creation of an anterior capsulotomy during cataract surgery. The LenSx includes a separate and distinct mode of operation, the "Capsule" Program, that performs anterior capsulotomy in an infringing manner, and for which there is no substantial noninfringing use. Using the LenSx for the FDA-approved indication of anterior capsulotomy during cataract surgery is not a staple article or commodity of commerce, and does not have a substantial noninfringing use. Upon information and belief, customers have no practical ability to modify or use the LenSx for the indicated use of anterior capsulotomy in a way to avoid infringement of the '725 patent.

282. Alcon has infringed and continues to infringe the '725 patent by supplying or causing to be supplied in or from the United States, without authority, all or a substantial portion of the components of the patented invention, including but not limited to the LenSx (in either assembled or unassembled form), parts and software for the LenSx, and consumables such as the LenSx SoftFit Patient Interface, where such components are uncombined in whole or in part, in such a manner as to actively induce the combination of such components outside of the United

States in a manner that would infringe the patent if such combination occurred within the United States, in violation of 35 U.S.C. § 271(f)(1). The components include but are not limited to the hardware and software components that are used to enable and perform the "Capsule" Program that performs the FDA-approved anterior capsulotomy in an infringing manner. Alcon's inducing acts include instructions on assembly and use of the LenSx and consumables for use with the LenSx, marketing the LenSx, and providing installation, maintenance, service, and/or repair of the LenSx. Alcon has stated that the "LenSx® Laser requires use of proprietary sterile disposable Patient Interfaces." Alcon has further stated "[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system." Additionally, upon information and belief, Alcon publishes and provides product documentation and educational materials that instruct and encourage its customers to use the LenSx for its FDA-approved indications for use and in an infringing manner, including providing the information relevant to each of the claim limitations that is referenced and/or quoted in the paragraphs above, with knowledge and/or with willful blindness that the induced acts constitute patent infringement.

283. Alcon has infringed and continues to infringe the '725 patent by supplying or causing to be supplied in or from the United States, without authority, at least one component of the patented invention, including but not limited to the LenSx (in either assembled or unassembled form), and parts and software for the LenSx, that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component(s) will be combined outside of the United States in a manner that infringe the patent if such combination occurred within the United States, in violation of 35 U.S.C. § 271(f)(2). The components include but are not limited to

the hardware and software components that are used to enable and perform the "Capsule" Program that performs the FDA-approved anterior capsulotomy in an infringing manner, including as set forth limitation-by-limitation in the paragraphs above, and for which there are no substantial noninfringing uses. Using the LenSx for the FDA-approved indicated uses of anterior capsulotomy during cataract surgery is not a staple article or commodity of commerce, and does not have a substantial noninfringing use. Upon information and belief, customers have no practical ability to modify or use the LenSx or the components thereto for the indicated use of anterior capsulotomy in a way to avoid infringement of the '725 patent.

284. Alcon is not licensed under the '725 patent.

285. The marking requirement of 35 U.S.C. § 287(a) has been satisfied through J&J Surgical Vision's marking of the Catalys® Precision Laser System.

286. J&J Surgical Vision has been damaged and will continue to be damaged by Alcon's infringement of the '725 patent.

287. J&J Surgical Vision has suffered and will continue to suffer irreparable harm unless and until Alcon's infringing activities are enjoined by this Court. J&J Surgical Vision does not have an adequate remedy at law.

288. Despite Alcon's knowledge of the '725 patent and of its infringing activities, Alcon has continued to manufacture, use, offer to sell, and/or sell the LenSx. Alcon's infringement of the '725 patent has been willful, making this an exceptional case and entitling J&J Surgical Vision to an award of increased damages and attorneys' fees.

COUNT X
Infringement of the '023 Patent

289. J&J Surgical Vision incorporates by reference the allegations set forth in paragraphs 1 through 288 as though fully set forth herein.

290. Alcon has directly and indirectly infringed, and continues to infringe, literally or under the doctrine of equivalents, one or more claims of the '023 patent, by making, using, offering to sell, and/or selling the LenSx and consumables in the United States, and supplying or causing to be supplied the LenSx and consumables from the United States for use abroad, without authority or license, in violation of 35 U.S.C. § 271.

291. For example, the LenSx meets each limitation of claim 1 of the '023 patent, which claims:

> A cataract surgery scanning system for treating target tissue in one or more of a cornea, limbus or sclera of a patient's eye, comprising:
>
> a treatment light source for generating a treatment light beam;
>
> a scanner for deflecting the light beam to form first and second treatment patterns of the treatment light beam under the control of a controller; and
>
> a delivery system comprising the controller operatively coupled to the treatment light source and the scanner, and programmed to: (i) deliver the first treatment pattern to a first target tissue selected from the group consisting of the cornea, limbus and sclera of the patient's eye to form a cataract incision therein that provides access to an eye chamber of the patient's eye, the incision to be formed by delivering the first treatment pattern only partially extending through the target tissue, and (ii) deliver the second treatment pattern to a second target tissue to form a relaxation incision along or near limbus tissue, or along corneal tissue-of the patient's eye.

292. The LenSx is a cataract surgery scanning system for treating target tissue in one or more of a cornea, limbus or sclera of a patient's eye. For example, Alcon has stated that "[t]he LenSx® Laser is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include … the creation of single plane and multi-plane arc cuts/incisions in the cornea. … The incision is achieved by contiguously placed microphotodisruptions scanned by a computer-controlled delivery system."

293. The LenSx has a treatment light source for generating a treatment light beam. For example, Alcon has stated that "[t]he LenSx® Laser uses focused femtosecond laser pulses to create incisions and separates tissue in the lens capsule, crystalline lens and cornea."

294. The LenSx has a scanner for deflecting the light beam to form first and second treatment patterns of the treatment light beam under the control of a controller. For example, Alcon has stated that "[a] computer-controlled scanning system directs the laser beam throughout a three-dimensional pattern to produce an incision." Alcon has also stated that "[t]he Primary Incision Pattern is used to create corneal incisions." Additionally, Alcon has stated that "[a]rcuate corneal cuts can be made using the Arcuate Incision Pattern."

295. The LenSx has a delivery system comprising the controller operatively coupled to the treatment light source and the scanner. For example, Alcon has stated that "[a] computer monitors and controls the beam energy, repetition rate, safety shutters, footswitch, laser diagnostics, the position of the scanners and the position of the scanning objective lens."

296. The LenSx is programmed to deliver the first treatment pattern to a first target tissue selected from the group consisting of the cornea, limbus and sclera of the patient's eye to form a cataract incision therein that provides access to an eye chamber of the patient's eye, the incision to be formed by delivering the first treatment pattern only partially extending through the target tissue. For example, Alcon has stated "[t]he Primary Incision Pattern is used to create corneal incisions." Alcon has also stated that "[t]he Primary Incision Pattern may represent a completely penetrating cut or a partial thickness cut."

297. The LenSx is programmed to deliver the second treatment pattern to a second target tissue to form a relaxation incision along or near limbus tissue, or along corneal tissue-of the patient's eye. For example, Alcon has stated "[a]rcuate corneal cuts can be made using the Arcuate

Incision Pattern. Arcuate Incision Pattern cuts are arc-shaped partial thickness cuts and are made in the cornea at a programmed diameter from the center."

298. Alcon's manufacture, use, offer to sell, and sale of the LenSx in the United States has infringed and continues to infringe the '023 patent under 35 U.S.C. § 271(a).

299. Alcon's customers in the United States have directly infringed and continue to directly infringe the '023 patent by using the LenSx for its FDA-approved indications (including corneal cuts/incisions during cataract surgery).

300. Alcon has actively induced and continues to actively induce infringement of the '023 patent by encouraging its customers to use the LenSx, with specific intent, knowledge and/or willful blindness that the induced acts constitute patent infringement, in violation of 35 U.S.C. § 271(b). Upon information and belief, Alcon's inducing acts include marketing the LenSx, supporting the ongoing use of the LenSx by providing consumables such as the LenSx SoftFit Patient Interface for use with the LenSx, and providing installation, maintenance, service, and/or repair of the LenSx. Alcon has stated that the "LenSx® Laser requires use of proprietary sterile disposable Patient Interfaces." Alcon has further stated "[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system." Alcon's inducing acts also include providing instructions to use the LenSx for its FDA-approved indications (including corneal cuts/incisions during cataract surgery) in an infringing manner, including providing the information relevant to each of the claim limitations that is referenced and/or quoted in the paragraphs above. Additionally, upon information and belief, Alcon has published and provided product documentation and educational materials that instruct and encourage its customers to use the LenSx for its FDA-approved indications in an infringing manner, with knowledge and/or with willful blindness that the induced acts constitute patent infringement. Moreover, upon information

and belief, Alcon warns customers in the Operator's Manual for the LenSx that its "instructions must be observed."

301. Alcon has known of the '023 patent and of its infringement prior to this litigation, and it is further on notice through this lawsuit. Alcon's knowledge of the '023 patent, together with its knowledge about the design and operation of the LenSx, gave Alcon knowledge that its customers' use of the LenSx constitutes patent infringement, because the language of the '023 patent claims plainly reads upon the LenSx. Alcon's knowledge of infringement is also demonstrated by its receipt of correspondence and infringement charts specifically identifying its infringing acts, the allegations contained in this amended complaint, its prior knowledge of the patent and the subject matter claimed, its statements touting the advantages of features that it knew to be patented, and the affirmative measures it took to address its risk of liability for patent infringement. Alcon's specific intent to induce infringement is demonstrated by its continued infringing acts despite this knowledge.

302. Alcon has infringed and continues to infringe the '023 patent by supplying or causing to be supplied in or from the United States, without authority, all or a substantial portion of the components of the patented invention, including but not limited to the LenSx (in either assembled or unassembled form), parts and software for the LenSx, and consumables such as the LenSx SoftFit Patient Interface, where such components are uncombined in whole or in part, in such a manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, in violation of 35 U.S.C. § 271(f)(1). The components include but are not limited to the hardware and software components that are used to enable and perform "Cornea Arcuate," "Cornea Primary," and "Cornea Secondary" Programs that perform the FDA-approved partial

thickness corneal cuts/incisions during cataract surgery in an infringing manner. Alcon's inducing acts include instructions on assembly and use of the LenSx and consumables for use with the LenSx, marketing the LenSx, and providing installation, maintenance, service, and/or repair of the LenSx. Alcon has stated that the "LenSx® Laser requires use of proprietary sterile disposable Patient Interfaces." Alcon has further stated "[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system." Additionally, upon information and belief, Alcon publishes and provides product documentation and educational materials that instruct and encourage its customers to use the LenSx for its FDA-approved indications for use and in an infringing manner, including providing the information relevant to each of the claim limitations that is referenced and/or quoted in the paragraphs above, with knowledge and/or with willful blindness that the induced acts constitute patent infringement.

303. Alcon is not licensed under the '023 patent.

304. The marking requirement of 35 U.S.C. § 287(a) has been satisfied through J&J Surgical Vision's marking of the Catalys® Precision Laser System.

305. J&J Surgical Vision has been damaged and will continue to be damaged by Alcon's infringement of the '023 patent.

306. J&J Surgical Vision has suffered and will continue to suffer irreparable harm unless and until Alcon's infringing activities are enjoined by this Court. J&J Surgical Vision does not have an adequate remedy at law.

307. Despite Alcon's knowledge of the '023 patent and of its infringing activities, Alcon has continued to manufacture, use, offer to sell, and/or sell the LenSx. Alcon's infringement of the '023 patent has been willful, making this an exceptional case and entitling J&J Surgical Vision to an award of increased damages and attorneys' fees.

COUNT XI
Infringement of the '024 Patent

308. J&J Surgical Vision incorporates by reference the allegations set forth in paragraphs 1 through 307 as though fully set forth herein.

309. Alcon has directly and indirectly infringed, and continues to infringe, literally or under the doctrine of equivalents, one or more claims of the '024 patent, by making, using, offering to sell, and/or selling the LenSx and consumables in the United States, and supplying or causing to be supplied the LenSx and consumables from the United States for use abroad, without authority or license, in violation of 35 U.S.C. § 271.

310. For example, the LenSx meets each limitation of claim 1 of the '024 patent, which claims:

> A cataract surgery method of treating target tissue in one or more of a cornea, limbus or sclera of a patient's eye, comprising:
>
> > generating a treatment light beam;
> >
> > deflecting the treatment light beam using a scanner to form first and second treatment patterns;
> >
> > delivering the first treatment pattern to a first target tissue selected from the group consisting of the cornea, limbus and sclera of the patient's eye to form a cataract incision that is sized to provide access to an eye chamber of the patient's eye for lens removal instrumentation; and
> >
> > delivering the second treatment pattern to a second target tissue to form a relaxation incision along or near limbus tissue or along corneal tissue anterior to the limbus tissue of the patient's eye to reduce astigmatism thereof,
> >
> > wherein the incision formed by delivering the first treatment pattern only partially extends through the target tissue.

311. The LenSx practices a cataract surgery method of treating target tissue in one or more of a cornea, limbus or sclera of a patient's eye. For example, Alcon has stated that "[t]he LenSx® Laser is indicated for use in patients undergoing cataract surgery for removal of the

crystalline lens. Intended uses in cataract surgery include … the creation of single plane and multi-plane arc cuts/incisions in the cornea. … The incision is achieved by contiguously placed microphotodisruptions scanned by a computer-controlled delivery system."

312. The LenSx generates a treatment light beam. For example, Alcon has stated that "[t]he LenSx® Laser uses focused femtosecond laser pulses to create incisions and separates tissue in the lens capsule, crystalline lens and cornea."

313. The LenSx deflects the treatment light beam using a scanner to form first and second treatment patterns. For example, Alcon has stated that "[a] computer-controlled scanning system directs the laser beam throughout a three-dimensional pattern to produce an incision." Alcon states that "[t]he Primary Incision Pattern is used to create corneal incisions." Additionally, Alcon has stated that "[a]rcuate corneal cuts can be made using the Arcuate Incision Pattern."

314. The LenSx delivers the first treatment pattern to a first target tissue selected from the group consisting of the cornea, limbus and sclera of the patient's eye to form a cataract incision that is sized to provide access to an eye chamber of the patient's eye for lens removal instrumentation. For example, Alcon has stated that "[t]he LenSx® Laser is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include … the creation of single plane and multi-plane arc cuts/incisions in the cornea." Alcon has also stated that "[t]he Primary Incision Pattern is used to create corneal incisions."

315. The LenSx delivers the second treatment pattern to a second target tissue to form a relaxation incision along or near limbus tissue or along corneal tissue anterior to the limbus tissue of the patient's eye to reduce astigmatism thereof, wherein the incision formed by delivering the first treatment pattern only partially extends through the target tissue. For example, Alcon has stated that "[a]rcuate corneal cuts can be made using the Arcuate Incision Pattern. Arcuate Incision

Pattern cuts are arc-shaped partial thickness cuts and are made in the cornea at a programmed diameter from the center." Alcon has also stated that "[t]he Primary Incision Pattern is used to create corneal incisions. … The Primary Incision Pattern may represent a completely penetrating cut or a partial thickness cut."

316. Alcon's use of the LenSx in the United States has infringed and continues to infringe the '024 patent under 35 U.S.C. § 271(a).

317. Alcon's customers in the United States have directly infringed and continue to directly infringe the '024 patent by using the LenSx for its FDA-approved indications (including corneal cuts/incisions during cataract surgery).

318. Alcon has actively induced and continues to actively induce infringement of the '024 patent by encouraging its customers to use the LenSx, with specific intent, knowledge and/or willful blindness that the induced acts constitute patent infringement, in violation of 35 U.S.C. § 271(b). Upon information and belief, Alcon's inducing acts include marketing the LenSx, supporting the ongoing use of the LenSx by providing consumables such as the LenSx SoftFit Patient Interface for use with the LenSx, and providing installation, maintenance, service, and/or repair of the LenSx. Alcon has stated that the "LenSx® Laser requires use of proprietary sterile disposable Patient Interfaces." Alcon has further stated "[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system." Alcon's inducing acts also include providing instructions to use the LenSx for its FDA-approved indications (including corneal cuts/incisions during cataract surgery) in an infringing manner, including providing the information relevant to each of the claim limitations that is referenced and/or quoted in the paragraphs above. Additionally, upon information and belief, Alcon has published and provided product documentation and educational materials that instruct and encourage its customers to use

the LenSx for its FDA-approved indications in an infringing manner, with knowledge and/or with willful blindness that the induced acts constitute patent infringement. Moreover, upon information and belief, Alcon warns customers in the Operator's Manual for the LenSx that its "instructions must be observed."

319. Alcon has known of the '024 patent and of its infringement prior to this litigation, and it is further on notice through this lawsuit. Alcon's knowledge of the '024 patent, together with its knowledge about the design and operation of the LenSx, gave Alcon knowledge that its customers' use of the LenSx constitutes patent infringement, because the language of the '024 patent claims plainly reads upon the LenSx. Alcon's knowledge of infringement is also demonstrated by its receipt of correspondence and infringement charts specifically identifying its infringing acts, the allegations contained in this amended complaint, its prior knowledge of the patent and the subject matter claimed, its statements touting the advantages of features that it knew to be patented, and the affirmative measures it took to address its risk of liability for patent infringement. Alcon's specific intent to induce infringement is demonstrated by its continued infringing acts despite this knowledge.

320. Alcon is not licensed under the '024 patent.

321. J&J Surgical Vision has been damaged and will continue to be damaged by Alcon's infringement of the '024 patent.

322. J&J Surgical Vision has suffered and will continue to suffer irreparable harm unless and until Alcon's infringing activities are enjoined by this Court. J&J Surgical Vision does not have an adequate remedy at law.

323. Despite Alcon's knowledge of the '024 patent and of its infringing activities, Alcon has continued to manufacture, use, offer to sell, and/or sell the LenSx. Alcon's infringement of the

'024 patent has been willful, making this an exceptional case and entitling J&J Surgical Vision to an award of increased damages and attorneys' fees.

COUNT XII
Infringement of the '648 Patent

324. J&J Surgical Vision incorporates by reference the allegations set forth in paragraphs 1 through 323 as though fully set forth herein.

325. Alcon has directly and indirectly infringed, and continues to infringe, literally or under the doctrine of equivalents, one or more claims of the '648 patent, by making, using, offering to sell, and/or selling the LenSx and consumables in the United States, and supplying or causing to be supplied the LenSx and consumables from the United States for use abroad, without authority or license, in violation of 35 U.S.C. § 271.

326. For example, the LenSx meets each limitation of claim 1 of the '648 patent, which claims:

> A laser surgical system for making incisions in ocular tissues during a cataract surgical procedure, the system comprising:
>
> a laser system comprising a scanning assembly;
>
> a laser operable to generate a laser beam configured to incise ocular tissue;
>
> an imaging device configured to acquire image data of at least a portion of the lens; and
>
> a control system operably coupled to the laser system and configured to:
>
> operate the imaging device to generate image data for the patient's crystalline lens;
>
> process the image data to determine an anterior capsule incision scanning pattern for scanning a focal zone of the laser beam for performing an anterior capsule incision; and
>
> operate the laser and the scanning assembly to scan the focal zone of the laser beam in the anterior capsule incision scanning pattern to perform the anterior capsule incision, wherein positioning of the

> focal zone is determined in part by the control system based on the image data.

327. The LenSx is a laser surgical system for making incisions in ocular tissues during a cataract surgical procedure. For example, Alcon has stated that "[t]he LenSx® Laser is indicated for use in patients undergoing cataract surgery … The LenSx® Laser creates incisions through tightly focused femtosecond laser pulses that cut tissue with micron-scale precision."

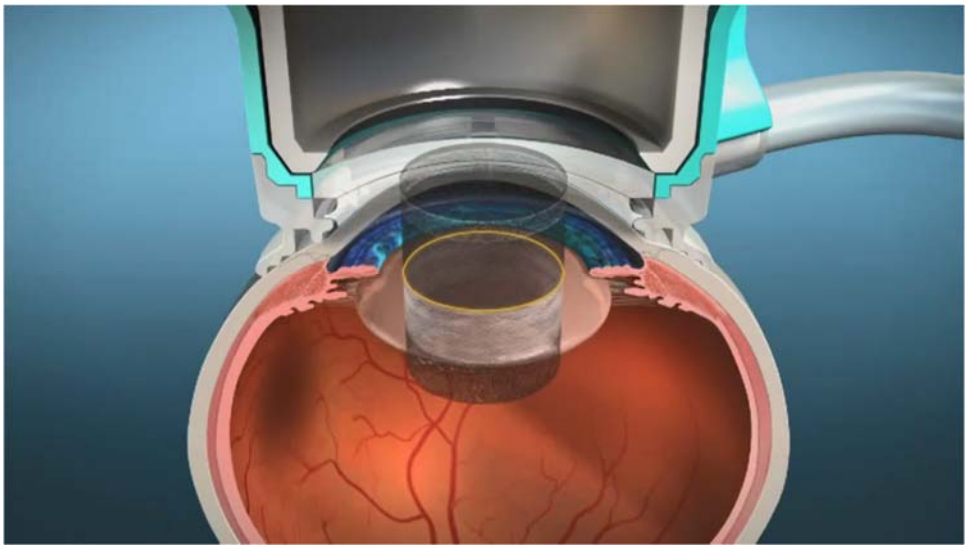
328. The LenSx has a laser system comprising a scanning assembly. For example, Alcon has stated that the LenSx has "[a] computer-controlled scanning system [that] directs the focused laser beam throughout a three-dimensional pattern to produce an incision."

329. The LenSx has a laser operable to generate a laser beam configured to incise ocular tissue. For example, Alcon has stated that the LenSx has "an ophthalmic surgical laser which uses focused femtosecond laser pulses to create incisions and to separate tissue within the lens capsule, crystalline lens, and the cornea. A femtosecond light pulse[] is focused into a sufficiently small spot in order to achieve photodisruption of the tissue inside the focus. A tiny volume of tissue, a few microns in diameter, is thereby photodisrupted at the laser focus. A computer-controlled scanning system directs the focused laser beam throughout a three-dimensional pattern to produce an incision."

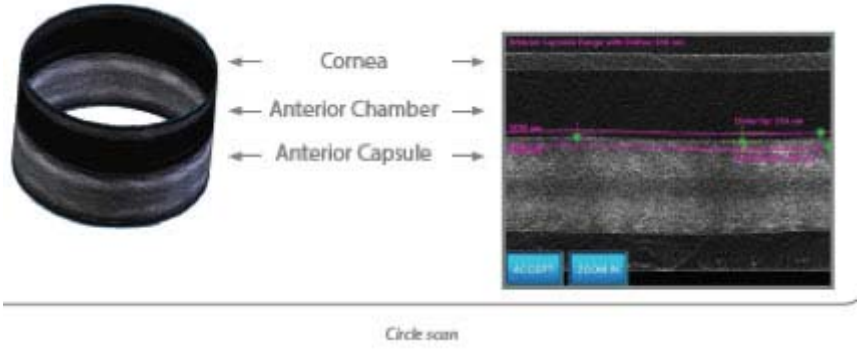
330. The LenSx has an imaging device configured to acquire image data of at least a portion of the lens. Upon information and belief, the LenSx uses a 3D spectral domain OCT imaging assembly. For example, Alcon has stated that its OCT imaging assembly is "a low power visible wavelength light source that is scanned throughout the transparent structures of the anterior chamber of the eye."

331. The LenSx has a control system operably coupled to the laser system and configured to operate the imaging device to generate image data for the patient's crystalline lens.

For example, Alcon has stated that in the LenSx, "a computer monitors and controls the beam energy, repetition rate, safety shutters, footswitch, laser diagnostics, the position of the scanners and the position of the scanning objective lens." Upon information and belief, the LenSx uses its OCT imaging assembly to generate what Alcon refers to as a circle scan. For example, Alcon has illustrated a circle scan as follows:



The circle scan provides an image of the patient's crystalline lens. For example, Alcon has shown an image of a circle scan as follows:



332. The LenSx has a control system operably coupled to the laser system and configured to process the image data to determine an anterior capsule incision scanning pattern for scanning a focal zone of the laser beam for performing an anterior capsule incision. For example,

Alcon has stated that the LenSx "includes an optical coherence tomography (OCT) based imaging device that assists in localizing specific target locations." Alcon has also stated that a "[c]ircle scan OCT image of the lens and capsule is displayed [on] the top right area of the Surgical Display. The circle scan is performed along the Capsule Pattern diameter as defined on the video microscope image of the eye." Alcon has also stated that "[t]he Capsule Pattern is used to perform an anterior capsulotomy of the crystalline lens." Alcon has also stated that "[t]he surgical effect is produced by scanning thousands of individual pulses" and the location of those pulses "is controlled by moving the focus of the laser beam to the desired surgical target location. A computer-controlled scanning system directs the laser beam throughout a three-dimensional pattern to produce an incision."

333. The LenSx has a control system operably coupled to the laser system and configured to operate the laser and the scanning assembly to scan the focal zone of the laser beam in the anterior capsule incision scanning pattern to perform the anterior capsule incision, wherein positioning of the focal zone is determined in part by the control system based on the image data. For example, Alcon has stated that the LenSx "includes an optical coherence tomography (OCT) based imaging device that assists in localizing specific target locations." Alcon has also stated that a "[c]ircle scan OCT image of the lens and capsule is displayed [on] the top right area of the Surgical Display. The circle scan is performed along the Capsule Pattern diameter as defined on the video microscope image of the eye." Alcon has also stated that "[t]he Capsule Pattern is used to perform an anterior capsulotomy of the crystalline lens." Alcon has also stated that "[t]he surgical effect is produced by scanning thousands of individual pulses" and the location of those pulses "is controlled by moving the focus of the laser beam to the desired surgical target location.

A computer-controlled scanning system directs the laser beam throughout a three-dimensional pattern to produce an incision."

334. Alcon's manufacture, use, offer to sell, and sale of the LenSx in the United States has infringed and continues to infringe the '648 patent under 35 U.S.C. § 271(a).

335. Alcon's customers in the United States have directly infringed and continue to directly infringe the '648 patent by using the LenSx for its FDA-approved indications (including anterior capsulotomy).

336. Alcon has actively induced and continues to actively induce infringement of the '648 patent by encouraging its customers to use the LenSx, with specific intent, knowledge and/or willful blindness that the induced acts constitute patent infringement, in violation of 35 U.S.C. § 271(b). Upon information and belief, Alcon's inducing acts include marketing the LenSx, supporting the ongoing use of the LenSx by providing consumables such as the LenSx SoftFit Patient Interface for use with the LenSx, and providing installation, maintenance, service, and/or repair of the LenSx. Alcon has stated that the "LenSx® Laser requires use of proprietary sterile disposable Patient Interfaces." Alcon has further stated "[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system." Alcon's inducing acts also include providing instructions to use the LenSx for its FDA-approved indications (including anterior capsulotomy) in an infringing manner, including providing the information relevant to each of the claim limitations that is referenced and/or quoted in the paragraphs above. Additionally, upon information and belief, Alcon has published and provided product documentation and educational materials that instruct and encourage its customers to use the LenSx for its FDA-approved indications in an infringing manner, with knowledge and/or with willful blindness that the induced acts constitute patent infringement. Moreover, upon information

and belief, Alcon warns customers in the Operator's Manual for the LenSx that its "instructions must be observed."

337. Alcon has known of the '648 patent and of its infringement prior to this litigation, and it is further on notice through this lawsuit. Alcon's knowledge of the '648 patent, together with its knowledge about the design and operation of the LenSx, gave Alcon knowledge that its customers' use of the LenSx constitutes patent infringement, because the language of the '648 patent claims plainly reads upon the LenSx. Alcon's knowledge of infringement is also demonstrated by its receipt of correspondence and infringement charts specifically identifying its infringing acts, the allegations contained in the original complaint, its prior knowledge of the patent and the subject matter claimed, its statements touting the advantages of features that it knew to be patented, and the affirmative measures it took to address its risk of liability for patent infringement. Alcon's specific intent to induce infringement is demonstrated by its continued infringing acts despite this knowledge.

338. Alcon has contributed to and continues to contribute to infringement of the '648 patent by offering to sell and selling the LenSx that its customers use to infringe the patent, in violation of 35 U.S.C. § 271(c). Alcon does so knowing that the LenSx constitutes a material part of the invention, and that it is especially made and especially adapted for use in an infringement of the patent. The LenSx is and consumables are designed and configured so that the customer will use the system to perform FDA-approved anterior capsulotomy in a manner that infringes the patent, including as set forth limitation-by-limitation in the paragraphs above. The customer necessarily infringes the patent when it uses the LenSx for the FDA-approved indicated use in the creation of an anterior capsulotomy during cataract surgery. The LenSx includes a separate and distinct mode of operation, the "Capsule" Program, that performs anterior capsulotomy in an

infringing manner, and for which there is no substantial noninfringing use. Using the LenSx for the FDA-approved indication of anterior capsulotomy during cataract surgery is not a staple article or commodity of commerce, and does not have a substantial noninfringing use. Upon information and belief, customers have no practical ability to modify or use the LenSx for the indicated use of anterior capsulotomy in a way to avoid infringement of the '648 patent.

339. Alcon has infringed and continues to infringe the '648 patent by supplying or causing to be supplied in or from the United States, without authority, all or a substantial portion of the components of the patented invention, including but not limited to the LenSx (in either assembled or unassembled form), parts and software for the LenSx, and consumables such as the LenSx SoftFit Patient Interface, where such components are uncombined in whole or in part, in such a manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, in violation of 35 U.S.C. § 271(f)(1). The components include but are not limited to the hardware and software components that are used to enable and perform the "Capsule" Program that performs the FDA-approved anterior capsulotomy in an infringing manner. Alcon's inducing acts include instructions on assembly and use of the LenSx and consumables for use with the LenSx, marketing the LenSx, and providing installation, maintenance, service, and/or repair of the LenSx. Alcon has stated that the "LenSx® Laser requires use of proprietary sterile disposable Patient Interfaces." Alcon has further stated "[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system." Additionally, upon information and belief, Alcon publishes and provides product documentation and educational materials that instruct and encourage its customers to use the LenSx for its FDA-approved indications for use and in an infringing manner, including providing the information relevant to

each of the claim limitations that is referenced and/or quoted in the paragraphs above, with knowledge and/or with willful blindness that the induced acts constitute patent infringement.

340. Alcon has infringed and continues to infringe the '648 patent by supplying or causing to be supplied in or from the United States, without authority, at least one component of the patented invention, including but not limited to the LenSx (in either assembled or unassembled form), and parts and software for the LenSx, that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component(s) will be combined outside of the United States in a manner that infringe the patent if such combination occurred within the United States, in violation of 35 U.S.C. § 271(f)(2). The components include but are not limited to the hardware and software components that are used to enable and perform the "Capsule" Program that performs the FDA-approved anterior capsulotomy in an infringing manner, including as set forth limitation-by-limitation in the paragraphs above, and for which there are no substantial noninfringing uses. Using the LenSx for the FDA-approved indicated uses of anterior capsulotomy during cataract surgery is not a staple article or commodity of commerce, and does not have a substantial noninfringing use. Upon information and belief, customers have no practical ability to modify or use the LenSx or the components thereto for the indicated uses of anterior capsulotomy in a way to avoid infringement of the '648 patent.

341. Alcon is not licensed under the '648 patent.

342. The marking requirement of 35 U.S.C. § 287(a) has been satisfied through J&J Surgical Vision's marking of the Catalys® Precision Laser System.

343. J&J Surgical Vision has been damaged and will continue to be damaged by Alcon's infringement of the '648 patent.

344. J&J Surgical Vision has suffered and will continue to suffer irreparable harm unless and until Alcon's infringing activities are enjoined by this Court. J&J Surgical Vision does not have an adequate remedy at law.

345. Despite Alcon's knowledge of the '648 patent and of its infringing activities, Alcon has continued to manufacture, use, offer to sell, and/or sell the LenSx. Alcon's infringement of the '648 patent has been willful, making this an exceptional case and entitling J&J Surgical Vision to an award of increased damages and attorneys' fees.

COUNT XIII
Infringement of the '903 Patent

346. J&J Surgical Vision incorporates by reference the allegations set forth in paragraphs 1 through 345 as though fully set forth herein.

347. Alcon has directly and indirectly infringed, and continues to infringe, literally or under the doctrine of equivalents, one or more claims of the '903 patent, by making, using, offering to sell, and/or selling the LenSx and consumables in the United States, and supplying or causing to be supplied the LenSx and consumables from the United States for use abroad, without authority or license, in violation of 35 U.S.C. § 271.

348. For example, the LenSx meets each limitation of claim 1 of the '903 patent, which claims:

> A laser surgical system for making incisions in ocular tissues during a cataract surgical procedure, the system comprising:
>
> > a laser system comprising a scanning assembly, a laser operable to generate a laser beam configured to incise ocular tissue;
> >
> > an imaging device configured to acquire image data from locations distributed throughout a volume of a crystalline lens of the patient and

construct one or more images of the patient's eye tissues from the image data, wherein the one or more images comprise an image of at least a portion of the crystalline lens; and

a control system operably coupled to the laser system and configured to:

operate the imaging device to generate image data of a continuous depth profile of the volume of the patient's crystalline lens;

identify one or more boundaries of the one or more tissue structures of the crystalline lens based at least in part on the image data;

process the image data to determine a lens fragmentation treatment region of the lens of the eye based at least in part upon the one or more boundaries, the lens fragmentation treatment region comprising a posterior cutting boundary located anterior to the posterior capsule of the lens;

process the image data to determine a lens fragmentation scanning pattern for scanning a focal zone of the laser beam for performing lens fragmentation, the lens fragmentation pattern comprising a scanning pattern at a plurality of depths within the lens fragmentation treatment region; and

operate the laser and the scanning assembly to scan the focal zone of the laser beam in the lens fragmentation scanning pattern consecutively at each of the plurality of depths within the lens fragmentation treatment region,

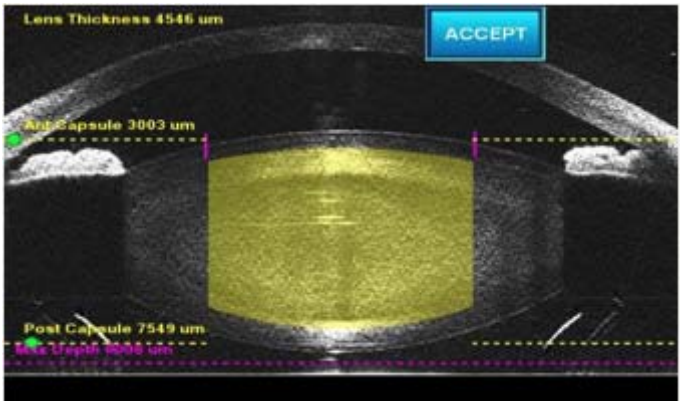
wherein positioning of the focal zone is guided by the control system based on the image data.

349. The LenSx is a laser surgical system for making incisions in ocular tissues during a cataract surgical procedure. For example, Alcon has stated that "[t]he LenSx® Laser is indicated for use in patients undergoing cataract surgery … The LenSx® Laser creates incisions through tightly focused femtosecond laser pulses that cut tissue with micron-scale precision."

350. The LenSx has a laser system comprising a scanning assembly, a laser operable to generate a laser beam configured to incise ocular tissue. For example, Alcon has stated that the LenSx has "an ophthalmic surgical laser which uses focused femtosecond laser pulses to create incisions and to separate tissue within the lens capsule, crystalline lens, and the cornea. A

femtosecond light pulse[] is focused into a sufficiently small spot in order to achieve photodisruption of the tissue inside the focus. A tiny volume of tissue, a few microns in diameter, is thereby photodisrupted at the laser focus. A computer-controlled scanning system directs the focused laser beam throughout a three-dimensional pattern to produce an incision."

351. The LenSx has an imaging device configured to acquire image data from locations distributed throughout a volume of a crystalline lens of the patient and construct one or more images of the patient's eye tissues from the image data, wherein the one or more images comprise an image of at least a portion of the crystalline lens. Upon information and belief, the LenSx uses a 3D spectral domain OCT imaging device. For example, Alcon has stated that "[t]he OCT consists of a low power visible wavelength light source that is scanned throughout the transparent structures of the anterior chamber of the eye. Light scattered from ocular structures and surfaces within the eye is analyzed to produce cross sectional images of the eye's anterior segment. Various sectioned images may be produced, including a wide field line scan of the anterior chamber, magnified cross sections of the cornea at the points of planned incisions, and circle and line scans of the lens and capsule." Upon information and belief the LenSx uses its OCT imaging assembly to generate what Alcon refers to as a line scan. For example, Alcon has shown an image of a line scan as follows:



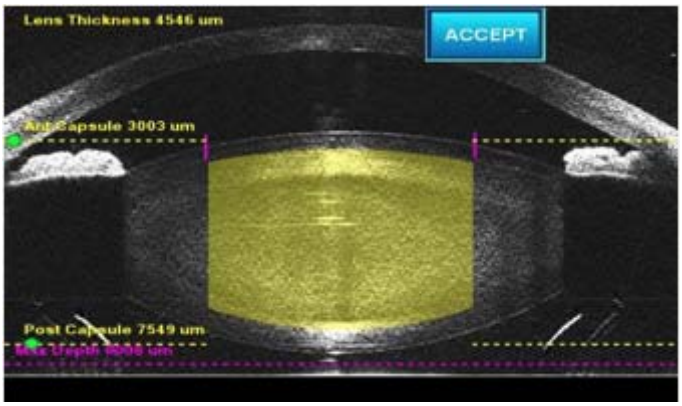
The line scan provides an image of at least a portion of the crystalline lens.

352. The LenSx has a control system operably coupled to the laser system and configured to operate the imaging device to generate image data of a continuous depth profile of the volume of the patient's crystalline lens. Upon information and belief, the LenSx uses a 3D spectral domain OCT imaging device. For example, Alcon has stated that its OCT imaging assembly is "a low power visible wavelength light source that is scanned throughout the transparent structures of the anterior chamber of the eye." Upon information and belief, the line scan depicted above shows a continuous depth profile of the volume of the patient's crystalline lens.

353. The LenSx has a control system operably coupled to the laser system and configured to identify one or more boundaries of the one or more tissue structures of the crystalline lens based at least in part on the image data. For example, with respect to the above image of a line scan, Alcon has stated that "[t]he Lens treatment volume is represented by a yellow semi-transparent solid. The upper arc of the solid matches the programmed Anterior Lens Curvature and the lower arc corresponds to the programmed Posterior Lens Curvature."

354. The LenSx has a control system operably coupled to the laser system and configured to process the image data to determine a lens fragmentation treatment region of the lens of the eye based at least in part upon the one or more boundaries, the lens fragmentation treatment region comprising a posterior cutting boundary located anterior to the posterior capsule of the lens. For example, Alcon has stated that "[a] computer monitors and controls the beam energy, repetition rate, safety shutters, footswitch, laser diagnostics, the position of the scanners and the position of the scanning objective lens." Alcon has also stated that the LenSx "includes an optical coherence tomography (OCT) based imaging device that assists in localizing specific target

locations." Upon information and belief, the LenSx displays a treatment region to the user. For example, Alcon has shown an image of a treatment region as follows:



Alcon has stated that "[t]he Lens treatment volume is represented by a yellow semi-transparent solid. The upper arc of the solid matches the programmed Anterior Lens Curvature and the lower arc corresponds to the programmed Posterior Lens Curvature." Alcon has stated that the "yellow solid" corresponds to the "volume of the Lens Pattern." Alcon has described the "Lens Pattern" as "used to perform phacofragmentation of the crystalline lens."

355. The LenSx has a control system operably coupled to the laser system and configured to process the image data to determine a lens fragmentation scanning pattern for scanning a focal zone of the laser beam for performing lens fragmentation, the lens fragmentation pattern comprising a scanning pattern at a plurality of depths within the lens fragmentation treatment region. For example, Alcon has stated that the "Lens Pattern is used to perform phacofragmentation of the crystalline lens. Lens Patterns may be specified as Chop, Cylinder or combined Chop and Cylinder patterns." Alcon has also stated that these "Lens phacofragmentation patterns are programmed to cut from at least 500 microns above the posterior capsule to at least 500 microns below the anterior capsule." Alcon has stated that the phacofragmentation "treatment pattern begins at the programmed posterior depth as an initial x-shaped scan is complete." Alcon has stated that the incision of the treatment pattern at the programmed posterior depth is "followed

by successive x-shaped scans created a few microns apart." Alcon has also stated that these "cuts proceed from the deepest point and move anteriorly, ending below the anterior capsule."

356. The LenSx has a control system operably coupled to the laser system and configured to operate the laser and the scanning assembly to scan the focal zone of the laser beam in the lens fragmentation scanning pattern consecutively at each of the plurality of depths within the lens fragmentation treatment region. For example, Alcon has stated that the phacofragmentation "treatment pattern begins at the programmed posterior depth as an initial x-shaped scan is complete." Alcon has stated that the incision of the treatment pattern at the programmed posterior depth is "followed by successive x-shaped scans created a few microns apart." Alcon has also stated that these "cuts proceed from the deepest point and move anteriorly, ending below the anterior capsule."

357. The LenSx has the above-described system wherein the positioning of the focal zone is guided by the control system based on the image data. For example, Alcon has stated that the LenSx "includes an optical coherence tomography (OCT) based imaging device that assists in localizing specific target locations." Alcon has also stated that "[l]ens phacofragmentation patterns are programmed to cut from at least 500 microns above the posterior capsule to at least 500 microns below the anterior capsule."

358. Alcon's manufacture, use, offer to sell, and sale of the LenSx in the United States has infringed and continues to infringe the '903 patent under 35 U.S.C. § 271(a).

359. Alcon's customers in the United States have directly infringed and continue to directly infringe the '903 patent by using the LenSx for its FDA-approved indications (including laser phacofragmentation).

360. Alcon has actively induced and continues to actively induce infringement of the '903 patent by encouraging its customers to use the LenSx, with specific intent, knowledge and/or willful blindness that the induced acts constitute patent infringement, in violation of 35 U.S.C. § 271(b). Upon information and belief, Alcon's inducing acts include marketing the LenSx, supporting the ongoing use of the LenSx by providing consumables such as the LenSx SoftFit Patient Interface for use with the LenSx, and providing installation, maintenance, service, and/or repair of the LenSx. Alcon has stated that the "LenSx® Laser requires use of proprietary sterile disposable Patient Interfaces." Alcon has further stated "[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system." Alcon's inducing acts also include providing instructions to use the LenSx for its FDA-approved indications (including laser phacofragmentation) in an infringing manner, including providing the information relevant to each of the claim limitations that is referenced and/or quoted in the paragraphs above. Additionally, upon information and belief, Alcon has published and provided product documentation and educational materials that instruct and encourage its customers to use the LenSx for its FDA-approved indications in an infringing manner, with knowledge and/or with willful blindness that the induced acts constitute patent infringement. Moreover, upon information and belief, Alcon warns customers in the Operator's Manual for the LenSx that its "instructions must be observed."

361. Alcon has known of the '903 patent and of its infringement prior to this litigation, and it is further on notice through this lawsuit. Alcon's knowledge of the '903 patent, together with its knowledge about the design and operation of the LenSx, gave Alcon knowledge that its customers' use of the LenSx constitutes patent infringement, because the language of the '903 patent claims plainly reads upon the LenSx. Alcon's knowledge of infringement is also

demonstrated by its receipt of correspondence and infringement charts specifically identifying its infringing acts, the allegations contained in the original complaint, its prior knowledge of the patent and the subject matter claimed, its statements touting the advantages of features that it knew to be patented, and the affirmative measures it took to address its risk of liability for patent infringement. Alcon's specific intent to induce infringement is demonstrated by its continued infringing acts despite this knowledge.

362. Alcon has contributed to and continues to contribute to infringement of the '903 patent by offering to sell and selling the LenSx that its customers use to infringe the patent, in violation of 35 U.S.C. § 271(c). Alcon does so knowing that the LenSx constitutes a material part of the invention, and that it is especially made and especially adapted for use in an infringement of the patent. The LenSx is designed and configured so that the customer will use the system to perform FDA-approved lens fragmentation in a manner that infringes the patent, including as set forth limitation-by-limitation in the paragraphs above. The customer necessarily infringes the patent when it uses the LenSx for the FDA-approved indicated use of a laser phacofragmentation during cataract surgery. The LenSx includes a separate and distinct mode of operation, the "Lens" Program, that performs laser phacofragmentation in an infringing manner, and for which there is no substantial noninfringing use. Using the LenSx for the FDA-approved indication of laser phacofragmentation during cataract surgery is not a staple article or commodity of commerce, and does not have a substantial noninfringing use. Upon information and belief, customers have no practical ability to modify or use the LenSx for the indicated use of laser phacofragmentation in a way to avoid infringement of the '903 patent.

363. Alcon has infringed and continues to infringe the '903 patent by supplying or causing to be supplied in or from the United States, without authority, all or a substantial portion

of the components of the patented invention, including but not limited to the LenSx (in either assembled or unassembled form), parts and software for the LenSx, and consumables such as the LenSx SoftFit Patient Interface, where such components are uncombined in whole or in part, in such a manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, in violation of 35 U.S.C. § 271(f)(1). The components include but are not limited to the hardware and software components that are used to enable and perform the "Lens" Program that performs the FDA-approved laser phacofragmentation in an infringing manner. Alcon's inducing acts include instructions on assembly and use of the LenSx and consumables for use with the LenSx, marketing the LenSx, and providing installation, maintenance, service, and/or repair of the LenSx. Alcon has stated that the "LenSx® Laser requires use of proprietary sterile disposable Patient Interfaces." Alcon has further stated "[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system." Additionally, upon information and belief, Alcon publishes and provides product documentation and educational materials that instruct and encourage its customers to use the LenSx for its FDA-approved indications for use and in an infringing manner, including providing the information relevant to each of the claim limitations that is referenced and/or quoted in the paragraphs above, with knowledge and/or with willful blindness that the induced acts constitute patent infringement.

364. Alcon has infringed and continues to infringe the '903 patent by supplying or causing to be supplied in or from the United States, without authority, at least one component of the patented invention, including but not limited to the LenSx (in either assembled or unassembled form), and parts and software for the LenSx, that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial

noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component(s) will be combined outside of the United States in a manner that infringe the patent if such combination occurred within the United States, in violation of 35 U.S.C. § 271(f)(2). The components include but are not limited to the hardware and software components that are used to enable and perform the "Lens" Program that performs the FDA-approved laser phacofragmentation in an infringing manner, including as set forth limitation-by-limitation in the paragraphs above, and for which there are no substantial noninfringing uses. Using the LenSx for the FDA-approved indicated use of laser phacofragmentation during cataract surgery is not a staple article or commodity of commerce, and does not have a substantial noninfringing use. Upon information and belief, customers have no practical ability to modify or use the LenSx or the components thereto for the indicated use of laser phacofragmentation in a way to avoid infringement of the '903 patent.

365. Alcon is not licensed under the '903 patent.

366. The marking requirement of 35 U.S.C. § 287(a) has been satisfied through J&J Surgical Vision's marking of the Catalys® Precision Laser System.

367. J&J Surgical Vision has been damaged and will continue to be damaged by Alcon's infringement of the '903 patent.

368. J&J Surgical Vision has suffered and will continue to suffer irreparable harm unless and until Alcon's infringing activities are enjoined by this Court. J&J Surgical Vision does not have an adequate remedy at law.

369. Despite Alcon's knowledge of the '903 patent and of its infringing activities, Alcon has continued to manufacture, use, offer to sell, and/or sell the LenSx. Alcon's infringement of the

'903 patent has been willful, making this an exceptional case and entitling J&J Surgical Vision to an award of increased damages and attorneys' fees.

COUNT XIV
Infringement of the '904 Patent

370. J&J Surgical Vision incorporates by reference the allegations set forth in paragraphs 1 through 369 as though fully set forth herein.

371. Alcon has directly and indirectly infringed, and continues to infringe, literally or under the doctrine of equivalents, one or more claims of the '904 patent, by making, using, offering to sell, and/or selling the LenSx and consumables in the United States, and supplying or causing to be supplied the LenSx and consumables from the United States for use abroad, without authority or license, in violation of 35 U.S.C. § 271.

372. For example, the LenSx meets each limitation of claim 1 of the '904 patent, which claims:

> A laser surgical system for making incisions in ocular tissues during a cataract surgical procedure, the system comprising:
>
> > a laser system comprising a scanning assembly, a laser operable to generate a laser beam configured to incise ocular tissue;
> >
> > an imaging device configured to acquire image data from locations distributed throughout a volume of a crystalline lens of the patient and construct one or more images of the patient's eye tissues from the image data, wherein the one or more images comprise an image of at least a portion of the crystalline lens; and
> >
> > a control system operably coupled to the laser system and configured to:
> >
> > > operate the imaging device to generate image data of a continuous depth profile of the volume of the patient's crystalline lens;
> > >
> > > identify one or more boundaries of crystalline lens based at least in part on the image data;
> > >
> > > > process the image data to determine a lens fragmentation scanning pattern for scanning a focal zone of the laser beam

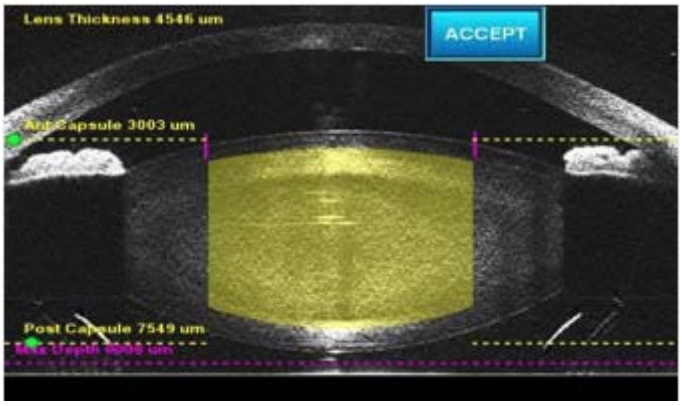
> for performing lens fragmentation, the lens fragmentation scanning pattern comprising a planar pattern at a first depth and at one or more additional depths anterior to the first depth;
>
> process the image data to determine a lens fragmentation treatment region of the lens of the eye based at least in part upon the one or more boundaries;
>
> operate the laser and the scanning assembly to scan the focal zone of the laser beam within the lens fragmentation treatment region in the planar pattern at the first depth and to subsequently direct the focal zone of the laser beam at the one or more additional depths anterior to the first depth, thereby effecting patterned laser cutting of lens tissue,
>
> wherein positioning of the focal zone is guided by the control system based on the image data.

373. The LenSx is a laser surgical system for making incisions in ocular tissues during a cataract surgical procedure. For example, Alcon has stated that "[t]he LenSx® Laser is indicated for use in patients undergoing cataract surgery … The LenSx® Laser creates incisions through tightly focused femtosecond laser pulses that cut tissue with micron-scale precision."

374. The LenSx has a laser system comprising a scanning assembly, a laser operable to generate a laser beam configured to incise ocular tissue. For example, Alcon has stated that the LenSx has "an ophthalmic surgical laser which uses focused femtosecond laser pulses to create incisions and to separate tissue within the lens capsule, crystalline lens, and the cornea. A femtosecond light pulse[] is focused into a sufficiently small spot in order to achieve photodisruption of the tissue inside the focus. A tiny volume of tissue, a few microns in diameter, is thereby photodisrupted at the laser focus. A computer-controlled scanning system directs the focused laser beam throughout a three-dimensional pattern to produce an incision."

375. The LenSx has an imaging device configured to acquire image data from locations distributed throughout a volume of a crystalline lens of the patient and construct one or more

images of the patient's eye tissues from the image data, wherein the one or more images comprise an image of at least a portion of the crystalline lens. Upon information and belief, the LenSx uses a 3D spectral domain OCT imaging device. For example, Alcon has stated that "[t]he OCT consists of a low power visible wavelength light source that is scanned throughout the transparent structures of the anterior chamber of the eye. Light scattered from ocular structures and surfaces within the eye is analyzed to produce cross sectional images of the eye's anterior segment. Various sectioned images may be produced, including a wide field line scan of the anterior chamber, magnified cross sections of the cornea at the points of planned incisions, and circle and line scans of the lens and capsule." Upon information and belief the LenSx uses its OCT imaging assembly to generate what Alcon refers to as a line scan. Alcon has shown an image of a line scan as follows:



The line scan provides an image of at least a portion of the crystalline lens.

376. The LenSx has a control system operably coupled to the laser system and configured to operate the imaging device to generate image data of a continuous depth profile of the volume of the patient's crystalline lens. Upon information and belief, the LenSx uses a 3D spectral domain OCT imaging device. For example, Alcon has stated that its OCT imaging assembly is "a low power visible wavelength light source that is scanned throughout the transparent structures of the anterior chamber of the eye." Upon information and belief, the line

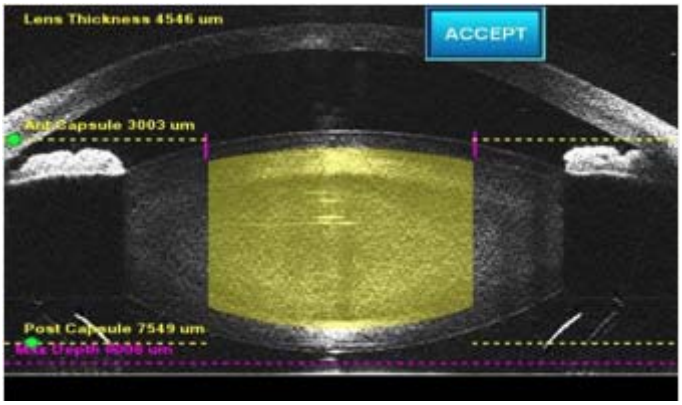
scan depicted above shows a continuous depth profile of the volume of the patient's crystalline lens.

377. The LenSx has a control system operably coupled to the laser system and configured to identify one or more boundaries of the crystalline lens based at least in part on the image data. For example, with respect to the above image of a line scan, Alcon has stated that "[t]he Lens treatment volume is represented by a yellow semi-transparent solid. The upper arc of the solid matches the programmed Anterior Lens Curvature and the lower arc corresponds to the programmed Posterior Lens Curvature."

378. The LenSx has a control system operably coupled to the laser system and configured to process the image data to determine a lens fragmentation scanning pattern for scanning a focal zone of the laser beam for performing lens fragmentation, the lens fragmentation scanning pattern comprising a planar pattern at a first depth and at one or more additional depths anterior to the first depth. For example, Alcon has stated that the "Lens Pattern is used to perform phacofragmentation of the crystalline lens. Lens Patterns may be specified as Chop, Cylinder or combined Chop and Cylinder patterns." Alcon has also stated that these "Lens phacofragmentation patterns are programmed to cut from at least 500 microns above the posterior capsule to at least 500 microns below the anterior capsule." Alcon has stated that the phacofragmentation "treatment pattern begins at the programmed posterior depth as an initial x-shaped scan is complete." Alcon has stated that the incision of the treatment pattern at the programmed posterior depth is "followed by successive x-shaped scans created a few microns apart." Alcon has also stated that these "cuts proceed from the deepest point and move anteriorly, ending below the anterior capsule."

379. The LenSx has a control system operably coupled to the laser system and configured to process the image data to determine a lens fragmentation treatment region of the lens

of the eye based at least in part upon the one or more boundaries. For example, Alcon has stated that "[a] computer monitors and controls the beam energy, repetition rate, safety shutters, footswitch, laser diagnostics, the position of the scanners and the position of the scanning objective lens." Alcon has also stated that the LenSx "includes an optical coherence tomography (OCT) based imaging device that assists in localizing specific target locations." Upon information and belief the LenSx uses its OCT imaging assembly to generate what Alcon refers to as a line scan. Alcon has shown an image of a line scan as follows:



Alcon has stated that "[t]he Lens treatment volume is represented by a yellow semi-transparent solid. The upper arc of the solid matches the programmed Anterior Lens Curvature and the lower arc corresponds to the programmed Posterior Lens Curvature." Upon information and belief the treatment volume includes the lens of the eye.

380. The LenSx has a control system operably coupled to the laser system and configured to operate the laser and the scanning assembly to scan the focal zone of the laser beam within the lens fragmentation treatment region in the planar pattern at the first depth and to subsequently direct the focal zone of the laser beam at the one or more additional depths anterior to the first depth, thereby effecting patterned laser cutting of lens tissue. For example, Alcon has stated that the "Lens Pattern is used to perform phacofragmentation of the crystalline lens. Lens Patterns may be specified as Chop, Cylinder or combined Chop and Cylinder patterns." Alcon has

also stated that these "Lens phacofragmentation patterns are programmed to cut from at least 500 microns above the posterior capsule to at least 500 microns below the anterior capsule." Alcon has stated that the phacofragmentation "treatment pattern begins at the programmed posterior depth as an initial x-shaped scan is complete." Alcon has stated that the incision of the treatment pattern at the programmed posterior depth is "followed by successive x-shaped scans created a few microns apart." Alcon has also stated that these "cuts proceed from the deepest point and move anteriorly, ending below the anterior capsule."

381. The LenSx has the above-described system wherein positioning of the focal zone is guided by the control system based on the image data. For example, Alcon has stated that the LenSx "includes an optical coherence tomography (OCT) based imaging device that assists in localizing specific target locations." Alcon has also stated that "[l]ens phacofragmentation patterns are programmed to cut from at least 500 microns above the posterior capsule to at least 500 microns below the anterior capsule."

382. Alcon's manufacture, use, offer to sell, and sale of the LenSx in the United States has infringed and continues to infringe the '904 patent under 35 U.S.C. § 271(a).

383. Alcon's customers in the United States have directly infringed and continue to directly infringe the '904 patent by using the LenSx for its FDA-approved indications (including laser phacofragmentation).

384. Alcon has actively induced and continues to actively induce infringement of the '904 patent by encouraging its customers to use the LenSx, with specific intent, knowledge and/or willful blindness that the induced acts constitute patent infringement, in violation of 35 U.S.C. § 271(b). Upon information and belief, Alcon's inducing acts include marketing the LenSx, supporting the ongoing use of the LenSx by providing consumables such as the LenSx SoftFit

Patient Interface for use with the LenSx, and providing installation, maintenance, service, and/or repair of the LenSx. Alcon has stated that the "LenSx® Laser requires use of proprietary sterile disposable Patient Interfaces." Alcon has further stated "[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system." Alcon's inducing acts also include providing instructions to use the LenSx for its FDA-approved indications (including laser phacofragmentation) in an infringing manner, including providing the information relevant to each of the claim limitations that is referenced and/or quoted in the paragraphs above. Additionally, upon information and belief, Alcon has published and provided product documentation and educational materials that instruct and encourage its customers to use the LenSx for its FDA-approved indications in an infringing manner, with knowledge and/or with willful blindness that the induced acts constitute patent infringement. Moreover, upon information and belief, Alcon warns customers in the Operator's Manual for the LenSx that its "instructions must be observed."

385. Alcon has known of the '904 patent and of its infringement prior to this litigation, and it is further on notice through this lawsuit. Alcon's knowledge of the '904 patent, together with its knowledge about the design and operation of the LenSx, gave Alcon knowledge that its customers' use of the LenSx constitutes patent infringement, because the language of the '904 patent claims plainly reads upon the LenSx. Alcon's knowledge of infringement is also demonstrated by its receipt of correspondence and infringement charts specifically identifying its infringing acts, the allegations contained in the original complaint, its prior knowledge of the patent and the subject matter claimed, its statements touting the advantages of features that it knew to be patented, and the affirmative measures it took to address its risk of liability for patent

infringement. Alcon's specific intent to induce infringement is demonstrated by its continued infringing acts despite this knowledge.

386. Alcon has contributed to and continues to contribute to infringement of the '904 patent by offering to sell and selling the LenSx that its customers use to infringe the patent, in violation of 35 U.S.C. § 271(c). Alcon does so knowing that the LenSx constitutes a material part of the invention, and that it is especially made and especially adapted for use in an infringement of the patent. The LenSx is designed and configured so that the customer will use the system to perform FDA-approved lens fragmentation in a manner that infringes the patent, including as set forth limitation-by-limitation in the paragraphs above. The customer necessarily infringes the patent when it uses the LenSx for the FDA-approved indicated use of a laser phacofragmentation during cataract surgery. The LenSx includes a separate and distinct mode of operation, the "Lens" Program, that performs laser phacofragmentation in an infringing manner. Using the LenSx for the FDA-approved indication of laser phacofragmentation during cataract surgery is not a staple article or commodity of commerce, and does not have a substantial noninfringing use. Upon information and belief, customers have no practical ability to modify or use the LenSx for the indicated use of laser phacofragmentation in a way to avoid infringement of the '904 patent.

387. Alcon has infringed and continues to infringe the '904 patent by supplying or causing to be supplied in or from the United States, without authority, all or a substantial portion of the components of the patented invention, including but not limited to the LenSx (in either assembled or unassembled form), parts and software for the LenSx, and consumables such as the LenSx SoftFit Patient Interface, where such components are uncombined in whole or in part, in such a manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United

States, in violation of 35 U.S.C. § 271(f)(1). The components include but are not limited to the hardware and software components that are used to enable and perform the "Lens" Program that performs the FDA-approved laser phacofragmentation in an infringing manner. Alcon's inducing acts include instructions on assembly and use of the LenSx and consumables for use with the LenSx, marketing the LenSx, and providing installation, maintenance, service, and/or repair of the LenSx. Alcon has stated that the "LenSx® Laser requires use of proprietary sterile disposable Patient Interfaces." Alcon has further stated "[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system." Additionally, upon information and belief, Alcon publishes and provides product documentation and educational materials that instruct and encourage its customers to use the LenSx for its FDA-approved indications for use and in an infringing manner, including providing the information relevant to each of the claim limitations that is referenced and/or quoted in the paragraphs above, with knowledge and/or with willful blindness that the induced acts constitute patent infringement.

388. Alcon has infringed and continues to infringe the '904 patent by supplying or causing to be supplied in or from the United States, without authority, at least one component of the patented invention, including but not limited to the LenSx (in either assembled or unassembled form), an parts and software for the LenSx, that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component(s) will be combined outside of the United States in a manner that infringe the patent if such combination occurred within the United States, in violation of 35 U.S.C. § 271(f)(2). The components include but are not limited to the hardware and software components that are used to enable and perform the "Lens" Program

that performs the FDA-approved laser phacofragmentation in an infringing manner, including as set forth limitation-by-limitation in the paragraphs above, and for which there are no substantial noninfringing uses. Using the LenSx for the FDA-approved indicated use of laser phacofragmentation during cataract surgery is not a staple article or commodity of commerce, and does not have a substantial noninfringing use. Upon information and belief, customers have no practical ability to modify or use the LenSx or the components thereto for the indicated use of laser phacofragmentation in a way to avoid infringement of the '904 patent.

389. Alcon is not licensed under the '904 patent.

390. The marking requirement of 35 U.S.C. § 287(a) has been satisfied through J&J Surgical Vision's marking of the Catalys® Precision Laser System.

391. J&J Surgical Vision has been damaged and will continue to be damaged by Alcon's infringement of the '904 patent.

392. J&J Surgical Vision has suffered and will continue to suffer irreparable harm unless and until Alcon's infringing activities are enjoined by this Court. J&J Surgical Vision does not have an adequate remedy at law.

393. Despite Alcon's knowledge of the '904 patent and of its infringing activities, Alcon has continued to manufacture, use, offer to sell, and/or sell the LenSx. Alcon's infringement of the '904 patent has been willful, making this an exceptional case and entitling J&J Surgical Vision to an award of increased damages and attorneys' fees.

COUNT XV
Infringement of the '356 Patent

394. J&J Surgical Vision incorporates by reference the allegations set forth in paragraphs 1 through 393 as though fully set forth herein.

395. Alcon has directly and indirectly infringed, and continues to infringe, literally or under the doctrine of equivalents, one or more claims of the '356 patent, by making, using, offering to sell, and/or selling the LenSx and consumables in the United States, and supplying or causing to be supplied the LenSx and consumables from the United States for use abroad, without authority or license, in violation of 35 U.S.C. § 271.

396. For example, the LenSx meets each limitation of claim 1 of the '356 patent, which claims:

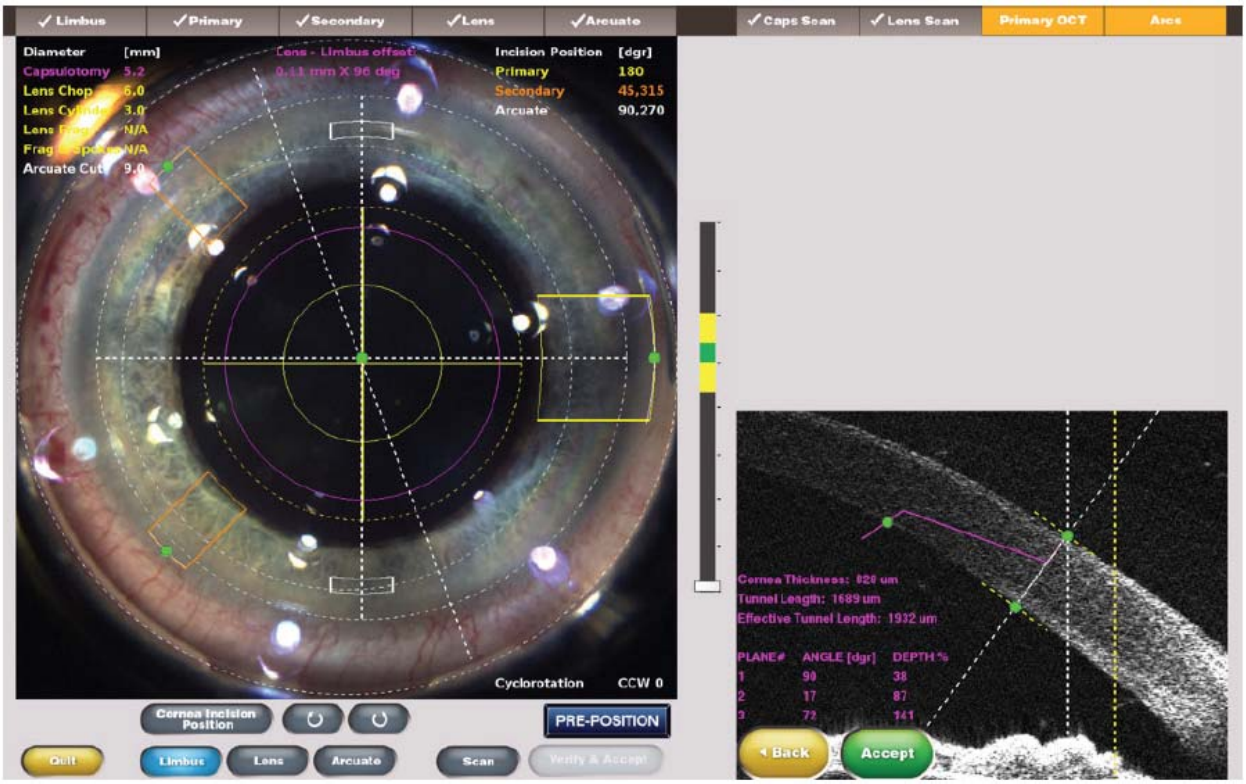
> An optical beam scanning system for incising target tissue in a patient's eye, the optical beam scanning system comprising:
>
> > a laser source configured to deliver a laser beam comprising a plurality of laser pulses, the laser beam being configured to produce optical breakdown and initiate a plasma-mediated process within the target tissue at a focal spot of the laser beam;
> >
> > an Optical Coherence Tomography (OCT) imaging device configured to generate signals that can be used to create an image of eye tissue that includes the cornea of the patient's eye;
> >
> > a delivery system for delivering the laser beam to the target tissue to form a cataract incision;
> >
> > a scanner operable to scan the focal spot of the laser beam to different locations within the patient's eye; and
> >
> > a controller operatively coupled to the laser source, the OCT imaging device and the scanner, the optical beam scanning, the controller programmed to:
> >
> > scan the eye tissue with the OCT device to generate imaging data for the target tissue that includes imaging data for the cornea;
> >
> > generate an incision pattern based at least in part on the imaging data, the incision pattern forming one or more relaxation incisions into the cornea, wherein each of the relaxation incision extends in an angular direction for a predetermined length less than a full circle, and wherein at least one of the one or more relaxation incisions is a partially penetrating incision that leaves an un-incised tissue thickness; and
> >
> > scan the focal spot of the laser beam in the incision pattern, wherein the focal spot of the laser beam is guided based on the imaging data so that the

focal spot of the laser beam is scanned from a posterior portion of the eye and proceeding anteriorly.

397. The LenSx has an optical beam scanning system for incising target tissue in a patient's eye. For example, Alcon has stated, "[t]he LenSx® Laser is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include an anterior capsulotomy, phacofragmentation, and the creation of single plane and multi-plane arc cuts/incisions in the cornea. … The incision is achieved by contiguously placed microphotodisruptions scanned by a computer-controlled delivery system."

398. The LenSx optical beam scanning system has a laser source configured to deliver a laser beam comprising a plurality of laser pulses, the laser beam being configured to produce optical breakdown and initiate a plasma-mediated process within the target tissue at a focal spot of the laser beam. For example, Alcon has stated, "[a]n all-solid-state laser source produces a kHz pulse train of femtosecond pulses. … Computer controlled scanning mirrors direct the light through a beam expander and through a focusing objective onto a spot at pre-determined depth within the eye." Alcon has stated that "[t]he light pulse is focused into a sufficiently small spot in order to achieve photodisruption of the tissue inside the focus. A tiny volume of tissue, a few microns in diameter, is photodisrupted at the laser focus. The surgical effect is produced by scanning thousands of individual pulses per second to produce a continuous incision or tissue separation. The location of the tissue photodisruption is controlled by moving the focus of the laser beam to the desired surgical target location." Alcon has also stated that "[t]he LenSx® Laser focuses a beam of low energy pulses of infrared light into the eye. Each pulse of energy creates photodisruption of a micro-volume of tissue at the focus of the beam." Upon information and belief photodisruption produced optical breakdown and initiates a plasma-mediated process within the target tissue.

399. The LenSx optical beam scanning system has an Optical Coherence Tomography (OCT) imaging device configured to generate signals that can be used to create an image of eye tissue that includes the cornea of the patient's eye. Alcon has stated "[a]n optical coherence tomography (OCT) imaging device and a video camera microscope (VM) are used to localize specific targets and to view the patient's eye." For example, Alcon has shown an OCT image as follows, which includes the cornea of the patient's eye:



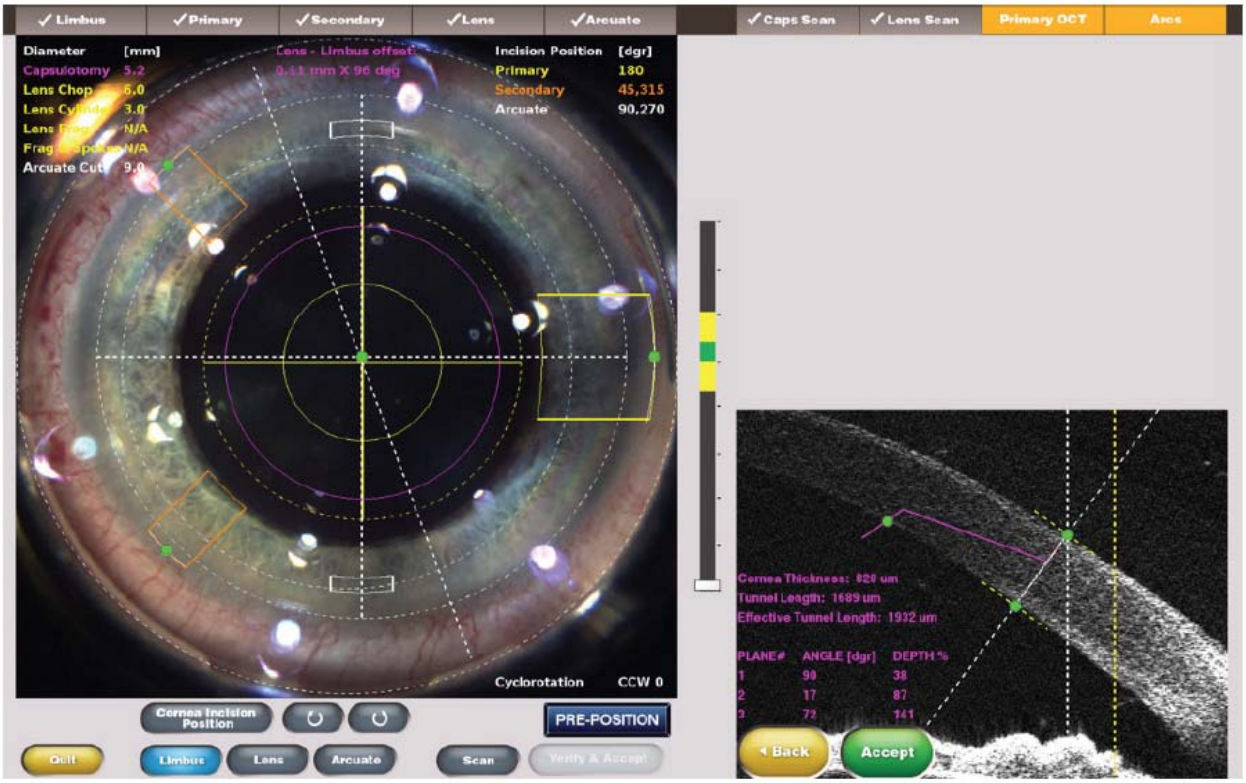
400. The LenSx optical beam scanning system has a delivery system for delivering the laser beam to the target tissue to form a cataract incision. For example, Alcon has stated that "[t]he LenSx® Laser focuses a beam of low energy pulses of infrared light into the eye. … By programming the size, shape and location of the scanning pattern, incisions are created." Alcon has also stated that "[t]he Primary Incision Pattern is used to create corneal incisions. … Secondary Incision Pattern creates a second corneal incision that is used to aid cataract surgery. The

Secondary Incision Pattern is similar to the Primary Incision Pattern with the exception that the Secondary Incision Pattern is only a single plane incision located along an arc on the corneal periphery."

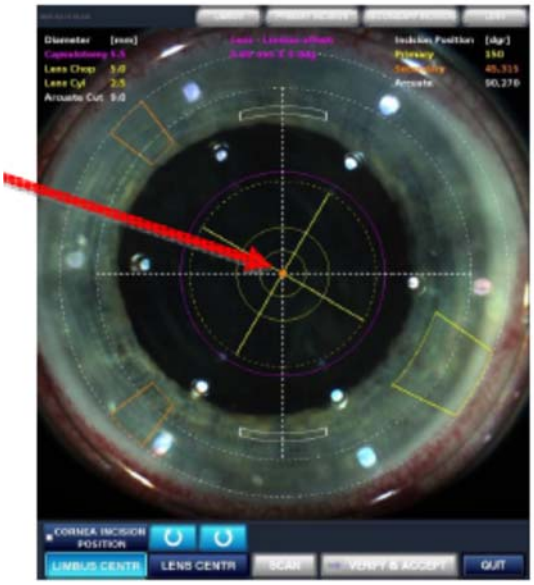
401. The LenSx optical beam scanning system has a scanner operable to scan the focal spot of the laser beam to different locations within the patient's eye. For example, Alcon has stated that "[c]omputer controlled scanning mirrors direct the light through a beam expander and through a focusing objective onto a spot at pre-determined depth within the eye."

402. The LenSx optical beam scanning system has a controller operatively coupled to the laser source, the OCT imaging device and the scanner, the optical beam scanning. For example, Alcon has stated that "[a] computer monitors and controls the beam energy, repetition rate, safety shutters, footswitch, laser diagnostics, the position of the scanners and the position of the scanning objective lens." Additionally, the "[c]omputer controlled scanning mirrors direct the light through a beam expander and through a focusing objective onto a spot at pre-determined depth within the eye." Alcon has also stated that "[t]he Surgical Display also includes an optical coherence tomography (OCT) based imaging device that assists in localizing specific target locations."

403. The LenSx controller is programmed to scan the eye tissue with the OCT device to generate imaging data for the target tissue that includes imaging data for the cornea. For example, Alcon has stated that "[a]n optical coherence tomography (OCT) imaging device and a video camera microscope (VM) are used to localize specific targets and to view the patient's eye." Additionally, Alcon has stated that "[v]arious sectioned images may be produced, including a wide field line scan of the anterior chamber, magnified cross sections of the cornea at the points of planned incisions, and circle and line scans of the lens and capsule." For example, Alcon has shown an OCT image as follows, which includes the cornea of the patient's eye:



404. The LenSx controller is programmed to generate an incision pattern based at least in part on the imaging data, the incision pattern forming one or more relaxation incisions into the cornea, wherein each of the relaxation incision extends in an angular direction for a predetermined length less than a full circle, and wherein at least one of the one or more relaxation incisions is a partially penetrating incision that leaves an un-incised tissue thickness. For example, Alcon has stated that "[a]n optical coherence tomography (OCT) imaging device and a video camera microscope (VM) are used to localize specific targets and to view the patient's eye." Alcon has arcuate corneal cuts as follows:.



The relaxation incisions (white curved boxes) extend in an angular direction for a predetermined length less than a full circle. Alcon has also stated that "[a]rcuate corneal cuts can be made using the Arcuate Incision Pattern. Arcuate Incision Pattern cuts are arc-shaped partial thickness cuts and are made in the cornea at a programmed diameter from the center."

405. The LenSx controller is programmed to scan the focal spot of the laser beam in the incision pattern, wherein the focal spot of the laser beam is guided based on the imaging data so that the focal spot of the laser beam is scanned from a posterior portion of the eye and proceeding anteriorly. For example, Alcon has stated that "[a]n all-solid-state laser source produces a kHz pulse train of femtosecond pulses. … Computer controlled scanning mirrors direct the light through a beam expander and through a focusing objective onto a spot at pre-determined depth within the eye." Alcon has also stated that "[w]hen scanned, the beam places individual photodisruption sites in a contiguous pattern to form continuous incisions." Furthermore, Alcon has stated "[a]rcuate Incision Pattern cuts start at a user-programmed posterior depth and progress in the anterior direction."

406. Alcon's manufacture, use, offer to sell, and sale of the LenSx in the United States has infringed and continues to infringe the '356 patent under 35 U.S.C. § 271(a).

407. Alcon's customers in the United States have directly infringed and continue to directly infringe the '356 patent by using the LenSx for its FDA-approved indications (including corneal cuts/incisions during cataract surgery).

408. Alcon has actively induced and continues to actively induce infringement of the '356 patent by encouraging its customers to use the LenSx, with specific intent, knowledge and/or willful blindness that the induced acts constitute patent infringement, in violation of 35 U.S.C. § 271(b). Upon information and belief, Alcon's inducing acts include marketing the LenSx, supporting the ongoing use of the LenSx by providing consumables such as the LenSx SoftFit Patient Interface for use with the LenSx, and providing installation, maintenance, service, and/or repair of the LenSx. Alcon has stated that the "LenSx® Laser requires use of proprietary sterile disposable Patient Interfaces." Alcon has further stated "[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system." Alcon's inducing acts also include providing instructions to use the LenSx for its FDA-approved indications (including corneal cuts/incisions during cataract surgery) in an infringing manner, including providing the information relevant to each of the claim limitations that is referenced and/or quoted in the paragraphs above. Additionally, upon information and belief, Alcon has published and provided product documentation and educational materials that instruct and encourage its customers to use the LenSx for its FDA-approved indications in an infringing manner, with knowledge and/or with willful blindness that the induced acts constitute patent infringement. Moreover, upon information and belief, Alcon warns customers in the Operator's Manual for the LenSx that its "instructions must be observed."

409. Alcon has known of the '356 patent and of its infringement prior to this litigation, and it is further on notice through this lawsuit. Alcon's knowledge of the '356 patent, together with its knowledge about the design and operation of the LenSx, gave Alcon knowledge that its customers' use of the LenSx constitutes patent infringement, because the language of the '356 patent claims plainly reads upon the LenSx. Alcon's knowledge of infringement is also demonstrated by its receipt of correspondence and infringement charts specifically identifying its infringing acts, the allegations contained in this amended complaint, its prior knowledge of the patent and the subject matter claimed, its statements touting the advantages of features that it knew to be patented, and the affirmative measures it took to address its risk of liability for patent infringement. Alcon's specific intent to induce infringement is demonstrated by its continued infringing acts despite this knowledge.

410. Alcon has infringed and continues to infringe the '356 patent by supplying or causing to be supplied in or from the United States, without authority, all or a substantial portion of the components of the patented invention, including but not limited to the LenSx (in either assembled or unassembled form), parts and software for the LenSx, and consumables such as the LenSx SoftFit Patient Interface, where such components are uncombined in whole or in part, in such a manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, in violation of 35 U.S.C. § 271(f)(1). The components include but are not limited to the hardware and software components that are used to enable and perform "Cornea Arcuate," "Cornea Primary," and "Cornea Secondary" Programs for the FDA-approved corneal cuts/incisions during cataract surgery in an infringing manner. Alcon's inducing acts include instructions on assembly and use of the LenSx and consumables for use with the LenSx, marketing

the LenSx, and providing installation, maintenance, service, and/or repair of the LenSx. Alcon has stated that the "LenSx® Laser requires use of proprietary sterile disposable Patient Interfaces." Alcon has further stated "[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system." Additionally, upon information and belief, Alcon publishes and provides product documentation and educational materials that instruct and encourage its customers to use the LenSx for its FDA-approved indications for use and in an infringing manner, including providing the information relevant to each of the claim limitations that is referenced and/or quoted in the paragraphs above, with knowledge and/or with willful blindness that the induced acts constitute patent infringement.

411. Alcon is not licensed under the '356 patent.

412. The marking requirement of 35 U.S.C. § 287(a) has been satisfied through J&J Surgical Vision's marking of the Catalys® Precision Laser System.

413. J&J Surgical Vision has been damaged and will continue to be damaged by Alcon's infringement of the '356 patent.

414. J&J Surgical Vision has suffered and will continue to suffer irreparable harm unless and until Alcon's infringing activities are enjoined by this Court. J&J Surgical Vision does not have an adequate remedy at law.

415. Despite Alcon's knowledge of the '356 patent and of its infringing activities, Alcon has continued to manufacture, use, offer to sell, and/or sell the LenSx. Alcon's infringement of the '356 patent has been willful, making this an exceptional case and entitling J&J Surgical Vision to an award of increased damages and attorneys' fees.

COUNT XVI
Infringement of the '548 Patent

416. J&J Surgical Vision incorporates by reference the allegations set forth in paragraphs 1 through 415 as though fully set forth herein.

417. Alcon has directly and indirectly infringed, and continues to infringe, literally or under the doctrine of equivalents, one or more claims of the '548 patent, by making, using, offering to sell, and/or selling the LenSx and consumables in the United States, and supplying or causing to be supplied the LenSx and consumables from the United States for use abroad, without authority or license, in violation of 35 U.S.C. § 271.

418. For example, the LenSx meets each limitation of claim 1 of the '548 patent, which claims:

A scanning system for treating target tissue in a patient's eye, comprising:

a) an ultrafast laser source configured to deliver a laser beam comprising a plurality of laser pulses;

b) an Optical Coherence Tomography (OCT) device configured to generate signals which may be used to create an image of the cornea and limbus of the eye of the patient;

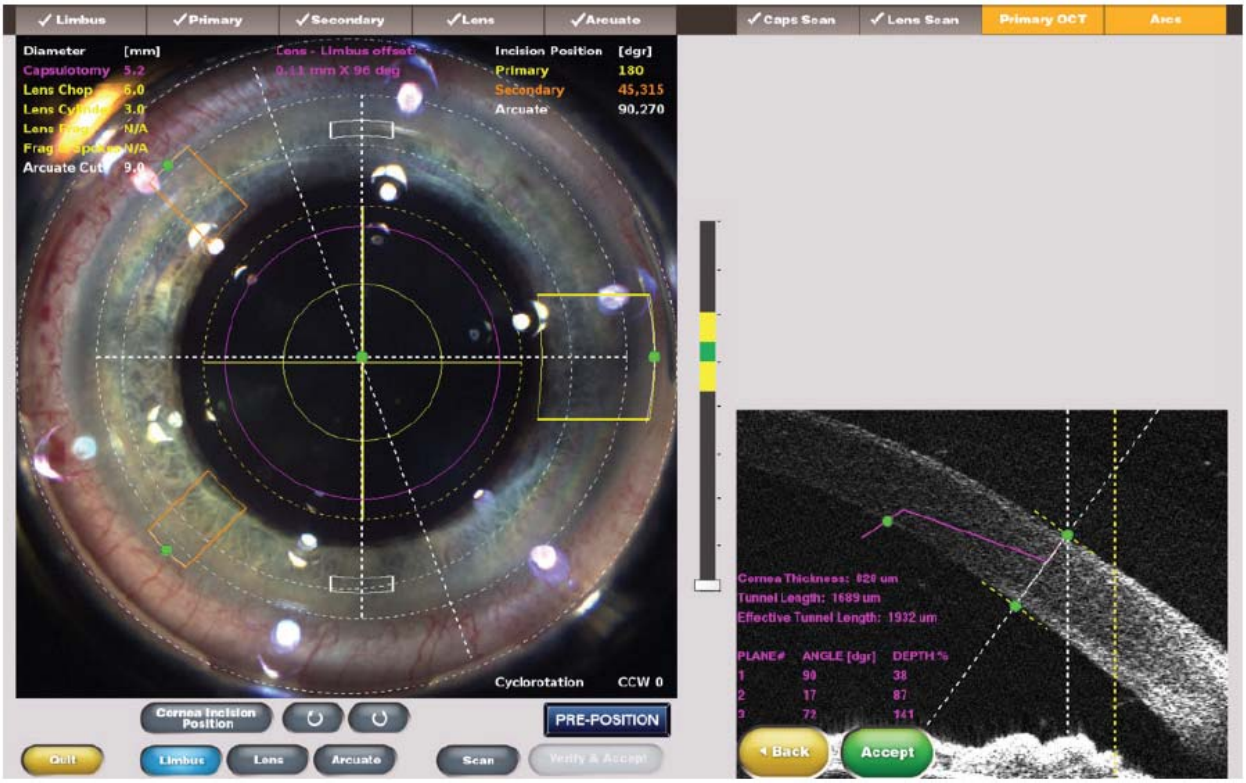
c) a scanner configured to focus and direct the laser beam in a pattern within the cornea or limbus to create incisions therein; and

d) a controller operatively coupled to the laser source and scanner programmed to determine a treatment pattern based upon the signals from the OCT device, the treatment pattern forming a cataract incision in the cornea that provides access for lens removal instrumentation to a crystalline lens of the patient's eye and one or more relaxation incisions in the cornea or limbus, wherein the cataract incision has an arcuate extent of less than 360 degrees in a top view, wherein the cataract incision includes a bevel shape in a cross-sectional view, the bevel shape including a first segment and a second segment which intersect each other at an angle, the cataract incision being entirely located in the cornea and intersecting both an anterior surface and a posterior surface of the cornea, and to control the scanner to scan the position of the laser beam in the treatment pattern.

419. The LenSx has a scanning system for treating target tissue in a patient's eye. For example, Alcon has stated "[t]he LenSx® Laser is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include … the creation of single plane and multi-plane arc cuts/incisions in the cornea. … The incision is achieved by contiguously placed microphotodisruptions scanned by a computer-controlled delivery system."

420. The LenSx has an ultrafast laser source configured to deliver a laser beam comprising a plurality of laser pulses. For example, Alcon has stated "[t]he LenSx® Laser System uses focused femtosecond laser pulses to create incisions and separates tissue in the lens capsule, crystalline lens and cornea."

421. The LenSx has an Optical Coherence Tomography (OCT) device configured to generate signals which may be used to create an image of the cornea and limbus of the eye of the patient. For example, Alcon has stated that "[a]n optical coherence tomography (OCT) imaging device and a video camera microscope (VM) are used to localize specific targets and to view the patient's eye." For example, Alcon has shown an OCT image as follows, which includes the cornea and limbus of the patient's eye:

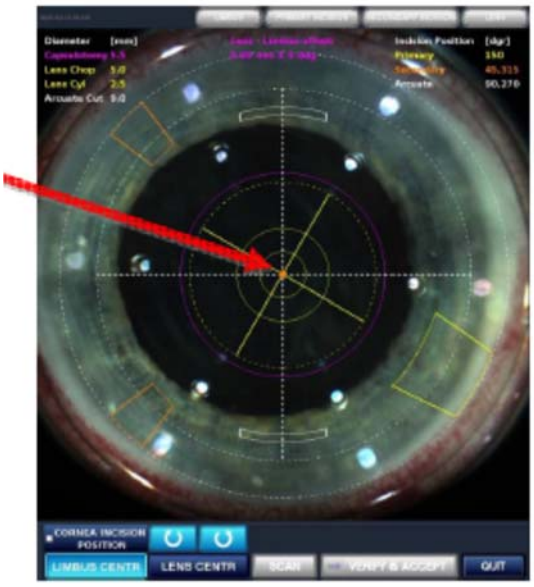


422. The LenSx has a scanner configured to focus and direct the laser beam in a pattern within the cornea or limbus to create incisions therein. For example, Alcon has stated "[t]he LenSx® Laser creates incisions through tightly focused femtosecond laser pulses that cut tissue with micron-scale precision. The incision is achieved by contiguously placed microphotodisruptions scanned by a computer-controlled delivery system." For example, Alcon has stated that "[t]he Primary Incision Pattern parameter screen allows the user to specify pattern geometry and laser scanning parameters. Its basic shape is an arc cut at the periphery of the cornea." Alcon has also stated that "[a]rcuate corneal cuts can be made using the Arcuate Incision Pattern."

423. The LenSx has a controller operatively coupled to the laser source and scanner programmed to determine a treatment pattern based upon the signals from the OCT device. For example, Alcon has stated that "[c]omputer controlled scanning mirrors direct the light through a

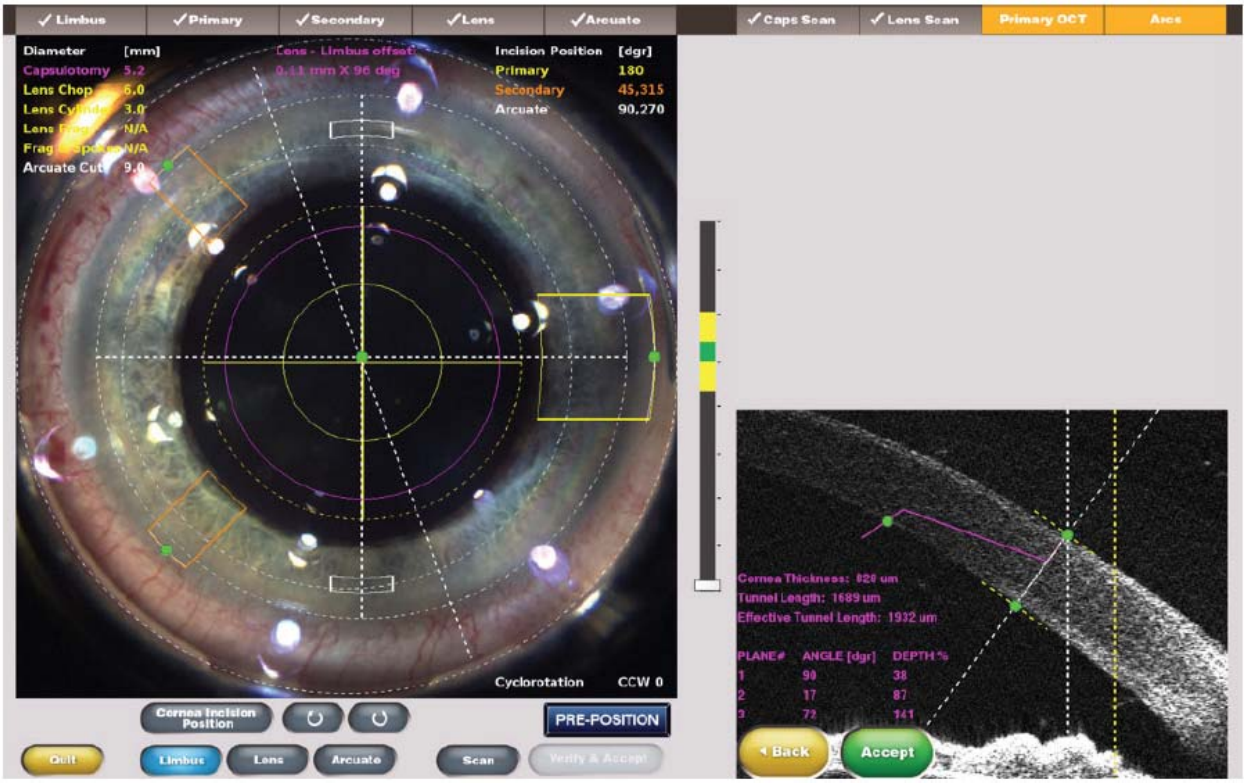
beam expander and through a focusing objective onto a spot at pre-determined depth within the eye." Alcon has also stated that "[t]he Surgical Display also includes an optical coherence tomography (OCT) based imaging device that assists in localizing specific target locations."

424. The LenSx treatment pattern forms a cataract incision in the cornea that provides access for lens removal instrumentation to a crystalline lens of the patient's eye and one or more relaxation incisions in the cornea or limbus, wherein the cataract incision has an arcuate extent of less than 360 degrees in a top view. For example, Alcon has stated that "[t]he LenSx® Laser is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens." Alcon has also stated that "[t]he Primary Incision Pattern is used to create corneal incisions. … The Primary Incision Pattern may represent a completely penetrating cut or a partial thickness cut. … The Primary Incision Pattern parameter screen allows the user to specify pattern geometry and laser scanning parameters. Its basic shape is an arc cut at the periphery of the cornea." Additionally, Alcon has stated that "[a]rcuate corneal cuts can be made using the Arcuate Incision Pattern. Arcuate Incision Pattern cuts are arc-shaped partial thickness cuts and are made in the cornea at a programmed diameter from the center." Alcon has shown the cataract incisions as follows:



The cataract incisions (yellow and orange boxes) have an arcuate extent of less than 360 degrees in a top view.

425. The LenSx cataract incision includes a bevel shape in a cross-sectional view, the bevel shape including a first segment and a second segment which intersect each other at an angle, the cataract incision being entirely located in the cornea and intersecting both an anterior surface and a posterior surface of the cornea, and to control the scanner to scan the position of the laser beam in the treatment pattern. For example, Alcon has also stated "[a]n X-Z cross-section of the Primary Incision Pattern is depicted. This representation of the incision is referred to as the Tunnel. The Tunnel may be composed of 1, 2 or 3 separate line segments representing the planes specified in the Primary Incision Pattern parameter programming step. … The numeric values of the tunnel length (distance from Epithelial control point to Tunnel control point), effective tunnel length (sum of distances of each plane making up the tunnel), corneal thickness are displayed. The angles and the percent depth of cornea for each plane making up the Primary Incision Pattern are also displayed." Alcon has stated that the "Primary Incision Pattern may represent a completely penetrating cut." Alcon has shown the segments intersecting both an anterior surface and a posterior surface of the cornea as follows:



Alcon has also stated that "[a] computer monitors and controls the beam energy, repetition rate, safety shutters, footswitch, laser diagnostics, the position of the scanners and the position of the scanning objective lens."

426. Alcon's manufacture, use, offer to sell, and sale of the LenSx in the United States has infringed and continues to infringe the '548 patent under 35 U.S.C. § 271(a).

427. Alcon's customers in the United States have directly infringed and continue to directly infringe the '548 patent by using the LenSx for its FDA-approved indications (including corneal cuts/incisions during cataract surgery).

428. Alcon has actively induced and continues to actively induce infringement of the '548 patent by encouraging its customers to use the LenSx, with specific intent, knowledge and/or willful blindness that the induced acts constitute patent infringement, in violation of 35 U.S.C. § 271(b). Upon information and belief, Alcon's inducing acts include marketing the LenSx,

supporting the ongoing use of the LenSx by providing consumables for use with the LenSx, and providing installation, maintenance, service, and/or repair of the LenSx. Alcon's inducing acts also include providing instructions to use the LenSx in an infringing manner, including providing the information relevant to each of the claim limitations that is referenced and/or quoted in the paragraphs above. Additionally, upon information and belief, Alcon has published and provided product documentation and educational materials that instruct and encourage its customers to use the LenSx for its FDA-approved indications (including corneal cuts/incisions during cataract surgery) in an infringing manner. For example, upon information and belief, Alcon warns customers in the Operator's Manual for the LenSx that its "instructions must be observed."

429. Alcon has known of the '548 patent and of its infringement prior to this litigation, and it is further on notice through this lawsuit. Alcon's knowledge of the '548 patent, together with its knowledge about the design and operation of the LenSx, gave Alcon knowledge that its customers' use of the LenSx constitutes patent infringement, because the language of the '548 patent claims plainly reads upon the LenSx. Alcon's knowledge of infringement is also demonstrated by its receipt of correspondence and infringement charts specifically identifying its infringing acts, the allegations contained in this amended complaint, its prior knowledge of the patent and the subject matter claimed, its statements touting the advantages of features that it knew to be patented, and the affirmative measures it took to address its risk of liability for patent infringement. Alcon's specific intent to induce infringement is demonstrated by its continued infringing acts despite this knowledge.

430. Alcon has infringed and continues to infringe the '548 patent by supplying or causing to be supplied in or from the United States, without authority, all or a substantial portion of the components of the patented invention, including but not limited to the LenSx (in either

assembled or unassembled form), parts and software for the LenSx, and consumables such as the LenSx SoftFit Patient Interface, where such components are uncombined in whole or in part, in such a manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, in violation of 35 U.S.C. § 271(f)(1). The components include but are not limited to the hardware and software components that are used to enable and perform "Cornea Arcuate," "Cornea Primary," and "Cornea Secondary" Programs that perform the FDA-approved fully penetrating corneal cuts/incisions during cataract surgery in an infringing manner. Alcon's inducing acts include instructions on assembly and use of the LenSx and consumables for use with the LenSx, marketing the LenSx, and providing installation, maintenance, service, and/or repair of the LenSx. Alcon has stated that the "LenSx® Laser requires use of proprietary sterile disposable Patient Interfaces." Alcon has further stated "[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system." Additionally, upon information and belief, Alcon publishes and provides product documentation and educational materials that instruct and encourage its customers to use the LenSx for its FDA-approved indications for use and in an infringing manner, including providing the information relevant to each of the claim limitations that is referenced and/or quoted in the paragraphs above, with knowledge and/or with willful blindness that the induced acts constitute patent infringement.

431. Alcon is not licensed under the '548 patent.

432. The marking requirement of 35 U.S.C. § 287(a) has been satisfied through J&J Surgical Vision's marking of the Catalys® Precision Laser System.

433. J&J Surgical Vision has been damaged and will continue to be damaged by Alcon's infringement of the '548 patent.

434. J&J Surgical Vision has suffered and will continue to suffer irreparable harm unless and until Alcon's infringing activities are enjoined by this Court. J&J Surgical Vision does not have an adequate remedy at law.

435. Despite Alcon's knowledge of the '548 patent and of its infringing activities, Alcon has continued to manufacture, use, offer to sell, and/or sell the LenSx. Alcon's infringement of the '548 patent has been willful, making this an exceptional case and entitling J&J Surgical Vision to an award of increased damages and attorneys' fees.

COUNT XVII
Direct Infringement of the Copyrighted Computer Programs

436. J&J Surgical Vision incorporates by reference the allegations set forth in paragraphs 1 through 435 as though fully set forth herein.

437. AMO Development owns the Asserted Copyrights, which are valid and enforceable and protect the iFS® Laser computer programs and all copyrightable elements of those computer programs. The Asserted Copyrights were all properly registered with the U.S. Copyright Office prior to instituting this action for copyright infringement.

438. Alcon does not have authorization, license, or permission from J&J Surgical Vision to reproduce, prepare derivative works based on, distribute to the public, or export any of J&J Surgical Vision's computer programs or any protected elements of those programs.

439. Through the acts alleged above, Alcon has violated, and is continuing the violate, J&J Surgical Vision's exclusive rights to reproduce, prepare derivative works based on, distribute to the public, and export the copyrighted iFS® Laser computer programs, in violation of 17 U.S.C. §§ 106, 501, and 602.

440. On information and belief, when developing, adopting, and marketing its LenSx, Alcon was and remains aware that the iFS® Laser computer programs are protected by copyright,

or acted or is acting in reckless disregard of the possibility that it was infringing and continues to infringe those copyrights. On information and belief, Alcon purposefully and without authorization incorporated into the LenSx software one or more protectable elements from the iFS® Laser computer programs, and Alcon was aware and continues to be aware that the LenSx software incorporates those protectable elements. At a minimum, Alcon was put on notice of its acts of copyright infringement as of July 14, 2020, when J&J Surgical Vision sent a letter identifying unambiguous evidence of such copying. Thus, Alcon's violations of J&J Surgical Vision's exclusive rights were and continue to be knowing, intentional, and willful.

COUNT XVIII

Secondary Liability for Infringement of the Copyrighted Computer Programs

441. J&J Surgical Vision incorporates by reference the allegations set forth in paragraphs 1 through 440 as though fully set forth herein.

442. AMO Development owns the Asserted Copyrights, which are valid and enforceable and protect the iFS® Laser computer programs and all copyrightable elements of those computer programs. The Asserted Copyrights were all properly registered with the U.S. Copyright Office prior to instituting this action for copyright infringement.

443. Users of the LenSx purchased from Alcon do not have authorization, license, or permission from J&J Surgical Vision to reproduce any of J&J Surgical Vision's computer programs.

444. Through the acts alleged above, users of the LenSx are engaged in acts of direct copyright infringement, including by reproducing the iFS® Laser computer programs.

445. On information and belief, when developing, marketing, and selling the LenSx, Alcon was and remains aware, or willfully blind, that its customers' use of LenSx would result in the infringement of J&J Surgical Vision's copyrights. Through the acts alleged above, Alcon

knowingly induced, caused, and/or materially contributed to, and continues to induce, cause, and/or materially contribute to, those acts of direct infringement by its LenSx customers. Accordingly, Alcon is liable for contributory copyright infringement.

446. On information and belief, Alcon has a direct financial interest in its LenSx customers' infringing activities. Alcon profits from ongoing use of the LenSx by its customers, including from the sale of consumable parts and the charging of per-procedure and maintenance fees, which as alleged above entails the infringement of the copyrighted iFS® Laser computer programs. On information and belief, Alcon also has the right and ability to supervise or control its customers' use of the LenSx (and thus, its LenSx customers' infringing activities). Alcon could prevent its LenSx customers' acts of infringement by, among other things, declining to sell the necessary consumable parts to those customers or by providing software updates that would replace the infringing software on its customers' devices. Accordingly, Alcon is liable for vicarious copyright infringement.

PRAYER FOR RELIEF

WHEREFORE, J&J Surgical Vision prays for a judgment that:

A. Alcon has infringed and, unless enjoined, will continue to infringe the Asserted Patents and Asserted Copyrights;

B. Enjoins Alcon and its officers, agents, servants, employees, attorneys, licensees, successors, customers, and all other persons acting in concert or participation with them, from further infringement of the Asserted Patents and Asserted Copyrights;

C. Awards J&J Surgical Vision damages adequate to compensate for Alcon's infringement of the Asserted Patents, including an accounting and/or supplemental damages for any infringing sales not presented at trial and through final judgment, together with pre-judgment and post-judgment interest as allowed by law, and other damages permitted under 35 U.S.C. § 284;

D. Declares Alcon's infringement of the Asserted Patents to be willful and awards enhanced damages in an amount to be treble the amount of compensatory damages as justified under 35 U.S.C. § 284;

E. Declares that this is an exceptional case under 35 U.S.C. § 285, and awards J&J Surgical Vision reasonable attorneys' fees, including pre-judgment interest on such fees;

F. Orders Alcon to return all copies of J&J Surgical Vision's copyrighted computer programs;

G. Awards actual damages and infringer's profits under 17 U.S.C. § 504(b) for Alcon's infringement of the Asserted Copyrights;

H. Orders impoundment or destruction of all infringing articles under 17 U.S.C. § 503, including, as necessary, while the present action is pending;

I. Awards pre-judgment and post-judgment interest, costs, and expenses; and

J. Awards such other and further relief as this Court deems just and proper.

JURY DEMAND

J&J Surgical Vision hereby demands trial by jury on all issues so triable.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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September 28, 2020

CERTIFICATE OF SERVICE

I hereby certify that on September 28, 2020, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on September 28, 2020, upon the following in the manner indicated:

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